United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 738-R-06-007
August 2006

Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the draft risk assessments for the antimicrobials, chlorine dioxide and sodium chlorite. The enclosed Reregistration Eligibility Decision (RED) document was approved on August 3, 2006. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for chlorine dioxide and sodium chlorite and the associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for chlorine dioxide are available to the public in EPA's Pesticide Docket EPA-HQ-**OPP-2006-0328** at: http://www.regulations.gov.

The chlorine dioxide and sodium chlorite RED was developed through EPA's public participation process, published in the Federal Register on April 26, 2006, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision-making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the chlorine dioxide and sodium chlorite risk assessment and the attached RED document concern only these particular pesticides. This RED presents the Agency's conclusions on the dietary, drinking water, residential, occupational and ecological risks posed by exposure to chlorine dioxide and sodium chlorite alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that chlorine dioxide and sodium chlorite will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by chlorine dioxide and sodium chlorite. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, ShaRon Carlisle, (703) 308-6427. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Emily Mitchell at (703) 308-8583.

Sincerely,

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY

DECISION

for

Chlorine Dioxide and Sodium Chlorite

Case Number 4023

Approved by:

_____
Frank T. Sanders, Director
Antimicrobials Division

_____
Date

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NTP	National Toxicology Program
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RAC	Raw Agricultural Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Chlorine Dioxide and Sodium Chlorite and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of chlorine dioxide and sodium chlorite that pose risks of concern. As a result of this review, EPA has determined that chlorine dioxide and sodium chlorite containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document. The Inorganic Chlorates Reregistration Eligibility Decision (RED) (PC code 073301), determined that sodium chlorate tolerances were safe provided a safety finding could be made for chlorine dioxide and sodium chlorite. This decision fulfills that condition.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reregistration assessments of the prior to 1984 chemicals. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for chlorine dioxide and sodium chlorite.

Chlorine dioxide and sodium chlorite are active ingredients in numerous products used in the control of bacteria, fungi, and algal slimes. In addition, chlorine dioxide and sodium chlorite are used as material preservatives and as disinfectants. At this time, products containing chlorine dioxide and sodium chlorite are intended for agricultural, commercial, industrial, medical and residential use. The agricultural premises and equipment uses include the disinfection of hard surfaces and equipment (such as hatching facilities and mushroom houses) and water systems (such as chiller water and humidification water in poultry houses). Commercial, industrial, and medical uses include disinfection of ventilation systems, hard surfaces (e.g., floors, walls, and laboratory equipment), water systems, pulp/paper mills, and food rinses. Residential uses include disinfection of hard surfaces (e.g., floors, bathrooms), heating ventilating and air-conditioning (HVAC) systems, and treatment of pool & spa water circulation systems. In addition, there is a continuous release gas product (sachet) for the home to control odors.

The Agency has concluded that the FQPA Safety Factor for chlorine dioxide should be removed (equivalent to 1X) based on: (1) the existence of a complete developmental and reproductive toxicity database; (2) the endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide is protective of potentially susceptible populations including children and (3) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredients chlorine dioxide and sodium chlorite. The FFDCA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorine dioxide and sodium chlorite and any other substances. Chlorine dioxide and sodium chlorite do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that chlorine dioxide and sodium chlorite has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative .

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of chlorine dioxide and sodium chlorite. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for chlorine dioxide and sodium chlorite referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket (EPA-HQ-OPP-2006-0328).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of chlorine dioxide and sodium chlorite and its regulatory history. Section III, Summary of Chlorine Dioxide and Sodium Chlorite Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

EPA first registered the aqueous form of chlorine dioxide for use as a disinfectant and a sanitizer in 1967. In industrial processes, chlorine dioxide is used as a disinfectant in water treatment, ammonia plants, pulp mills, oil fields, scrubbing systems, odor control systems, and the electronics industry. In 1988, EPA registered chlorine dioxide gas as a sterilant. Chlorine dioxide gas is registered for sterilizing manufacturing and laboratory equipment, environmental surfaces, tools, and clean rooms. One of the major antimicrobial uses of chlorine dioxide is to treat drinking water. In addition, the largest use of chlorine dioxide is the non-pesticidal bleaching use in the pulp and paper industry.

Both sodium chlorite and the active ingredient sodium chlorate are used as a precursor in the generation of chlorine dioxide. Sodium chlorite is a strong oxidizing agent that under oxidizing conditions is readily reduced to chlorite, another strong oxidizing agent, and to a lesser extent, chlorate. Sodium chlorate (included in the group of inorganic chlorates) is predominantly used in the pulp and paper manufacturing process and as a herbicide in agriculture. The antimicrobial uses of sodium chlorate are a minor part of the use pattern. The uses of sodium chlorate were assessed separately in the Inorganic Chlorates Reregistration Eligibility Decision (RED) (PC code 073301). The RED for the inorganic chlorates is available in the public docket at www.regulations.gov in docket number EPA-HQ-OPP-2005-0507. This RED will focus on the uses of chlorine dioxide/sodium chlorite.

B. Chemical Identification

CHLORINE DIOXIDE: PHYSICAL/CHEMICAL CHARACTERISTICS

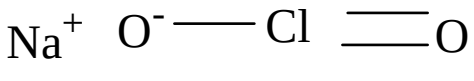
Chemical Name:	Chlorine dioxide, Chlorine (IV) oxide
Chemical Formula:	ClO_2
Chemical Structure:	
CAS#:	10049-04-4
Molecular Weight:	67.45 g/mol
Color:	Gas phase- Yellow green to orange Liquid phase- reddish brown
Melting Point:	-59 ^{o} C
Boiling Point:	11 ^{o} C
Odor:	Strongly pungent, chlorine-like
Physical State:	Gas at room temperature
Density:	1.64 g/ml at 0 ^{o} C (liquid) 1.614 g/ml at 10 ^{o} C (liquid)

Vapor Pressure:	490 mm Hg (0^{o} C) >760 mm Hg (25 ^{o} C)
Stability:	Unstable, estimated half life in water ~ 25 minutes*
Solubility (water):	3.01 g/L at 25 ^{o} C and 34. 5 mm Hg**

Chlorine dioxide is explosive at > -40 ^{o} C, and its explosive velocity in air is 50 m/s. It is highly miscible in water up to 60 g/L and is highly unstable in sunlight.

In aqueous solutions at pH>10, chlorine dioxide will hydrolyze to form chlorate and chlorite ions. In neutral or near neutral solutions (4< pH <10) chlorine dioxide is relatively stable and exists as a free radical in water. The rate of the hydrolysis reaction between water and chlorine dioxide is about ten million times slower than that of chlorine at neutral pH.

SODIUM CHLORITE: PHYSICAL/CHEMICAL CHARACTERISTICS

Chemical Name:	Sodium chlorite
Synonyms(s):	Chlorous acid, sodium salt
Chemical Formula:	$NaClO_2$
Chemical Structure:	
CAS#:	7758-19-2
Molecular Weight:	90.45 g/mol
Color:	White
Melting Point:	180-200 ^{o} C (decomposes)
Boiling Point:	n/a
Physical State:	Solid
Density:	2.468 g/ml (as a solid)
Vapor Pressure:	n/a
Stability:	*Stable at Room Temperature*
Solubility (water):	390 g/L at 30 ^{o} C
Compatibility:	Incompatible with organic matter, sulfur, powdered coal, and is a powerful oxidizer.

C. Use Profile

The following is information on the currently registered uses of chlorine dioxide and sodium chlorite, including an overview of use sites and application methods. A detailed table of the uses of sodium chlorate eligible for reregistration is available in Appendix A.

Type of Pesticide: Antimicrobial

Target Pests: Bacteria, fungi, and algal slimes.

Use Site:

Agricultural uses:	The agricultural premises and equipment uses include the disinfection of hard surfaces and equipment (such as hatching facilities and mushroom houses) and water systems (such as chiller water and humidification water in poultry houses).
Non-agricultural uses:	Commercial, industrial, and medical uses include disinfection of ventilation systems, hard surfaces (e.g., floors, walls, and laboratory equipment), water systems, pulp/paper mills, and food rinses
Residential:	Residential uses include disinfection of hard surfaces (e.g., floors, bathrooms), heating ventilating and air-conditioning (HVAC) systems, and treatment of pool & spa circulation systems. In addition, there is a continuous release gas product (sachet) for the home to control odors.
Use Classification:	General Use

Method and Rates of Application:

Equipment:	Foaming wand, sprayer, injector systems, mist and fogger, dip carcass, mop, pump, cloth and add to systems
Application Rates:	Concentrations of chlorine dioxide and sodium chlorite range from 5ppm to 5000ppm

Formulation Types: Soluble concentrates and ready-to-use liquid solutions

III. Summary of Chlorine Dioxide and Sodium Chlorite Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for chlorine dioxide and sodium chlorite. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2006-0328. Hard copies of these documents may be found in the OPP public docket under this same docket number. The OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

The human health risk assessment for chlorine dioxide and sodium chlorite incorporates potential exposure and risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children. For more information on the chlorine dioxide and sodium chlorite human health risk assessment, see Revised Chlorine Dioxide Risk Assessment, dated July 27, 2006, available at www.regulations.gov (EPA-HQ-OPP-2006-0328).

The Agency's use of human studies in the sodium chlorite risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

1. Toxicity of Chlorine Dioxide and Sodium Chlorite

A brief overview of the toxicity studies used for determining endpoints in the dietary risk assessments are outlined in Table 2. The Agency has reviewed all toxicity studies submitted for chlorine dioxide and has determined that the toxicological database is complete, reliable, and sufficient for reregistration. For more details on the toxicity and carcinogenicity of the chlorine dioxide and sodium chlorite, see the Chlorine Dioxide Toxicology Disciplinary Chapter, Case 4023, dated April, 5, 2006, which is available under docket number EPA-HQ-OPP-2006-0328.

Major features of the toxicology profile are presented below. The acute toxicity of chlorine dioxide is moderate by the oral route (toxicity category II). The acute toxicity of chlorine dioxide using sodium chlorite as the test material is considered minimal by the dermal route (toxicity category III). By the inhalation route using sodium chlorite as the test material, chlorine dioxide was moderately toxic. For primary eye irritation, chlorine dioxide was a mild irritant (toxicity category III), but the technical test material was not used. For primary dermal irritation, sodium chlorite was a primary irritant (toxicity category II). For dermal sensitization, there are no acceptable studies for chlorine dioxide or sodium chlorite. The acute toxicity profile

for chlorine dioxide is summarized in Table 1 below.

Table 1. Acute Toxicity Profile for Chlorine Dioxide/ Sodium Chlorite

Guideline Number	Study Type[a] / Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute oral (79% chlorine dioxide)	43558601	LD_{50} = 292 mg/kg (males) LD_{50} = 340 mg/kg (females)	II
870.1200 (§81-2)	Acute dermal (80% sodium chlorite)	40168704	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute inhalation (80.6% sodium chlorite)	42484101	LC_{50} = 0.29 mg/L	II
870.2400 (§81-4)	Primary eye irritation (2% chlorine dioxide)	43441903	Mild irritant	III
870.2500 (§81-5)	Primary dermal irritation (80% sodium chlorite)	40168704	Primary irritant	II
870.2600 (§81-6)	Dermal sensitization	No acceptable sensitization study available.		

[a] The available acute studies are all graded as acceptable. An acceptable dermal sensitization study is not available in the database.

The doses and toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 2 below.

Table 2: Summary of Toxicological Doses and Endpoint Selection for Chlorine Dioxide/ Sodium Chlorite

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	UF/MOE for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An acute dietary endpoint was not identified in the database for chlorine dioxide. This risk assessment is not required.		
Chronic Dietary	NOAEL = 3 mg/kg/day	UF = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic PAD =** 0.03 mg/kg/day	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups
Carcinogenicity	No cancer data is available for chlorine dioxide.		

General Toxicity Observations

Subchronic

Subchronic oral toxicity studies conducted with chlorine dioxide showed significant reductions in body weight increases and decreases in food consumption at 200 mg/L, the highest dose tested. Significant reductions in water consumption were observed in males and in females. Absolute liver weights were decreased in males at ‡ 50 mg/L, and absolute spleen weights were decreased in females at ‡ 25 mg/L. The LOAEL is 25 mg/L, based on a significant increase in the incidence of nasal lesions. No exposure-related deaths were reported in this study.

Subchronic oral toxicity studies conducted with sodium chlorite showed increased salivation, significantly decreased erythrocyte counts, and decreased total serum protein levels, and effects in the blood. During this study four animals died during treatment. It should be noted that one exposure-related death was observed in a range-finding study for the subchronic oral toxicity study each sex in the 200 mg/kg/day group on treatment days 2 and 3.

Dietary

An acute dietary endpoint was not identified in the database for chlorine dioxide; this risk assessment is not required for chlorine dioxide/sodium chlorite. The chronic dietary endpoint is 3 mg/kg/day, based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all dietary exposures.

Incidental Oral

The short-and intermediate-term oral endpoint is 3 mg/kg/day, based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all incidental oral exposures.

Dermal

The short-, intermediate-, and chronic-term dermal endpoint is based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all dermal exposures.

Inhalation

The inhalation route of exposure to chlorine dioxide is assessed for three distinct subpopulations: (1) occupational exposures (8 hours/day, 5 days/week), (2) one-time exposures

for residential uses (e.g., HVAC systems, mopping floors, etc), and (3) long-term exposure for continuous release products in the home (24 hours/day, 7 days/week). Several animal studies were used to develop reference concentrations (RfCs). The effects seen at various concentrations include rhinorrhea, altered respiration, respiratory infection, bronchial inflammation, alveolar congestion and hemorrhage, vascular congestion, and peribronchiolar edema. Readers are referred to USEPA (2000a) for a detailed review of the effects seen at specific concentrations and exposure durations along with the derivation of the RfC. In summary, the occupational RfC is determined to be 0.003 ppm and represents an 8-hour time weighted average (TWA). The one-time residential exposure scenario is represented by the RfC of 0.05 ppm and the RfC for long-term, continuous exposure is 0.00007 ppm. The RfC methodology incorporates the uncertainty factors into the concentration. For inhalation, the RfC is compared directly to the air concentration of interest. Inhalation risks are of concern if the air concentrations people are exposed to exceed the RfC.

Carcinogenicity

Chlorine dioxide has not been assessed for carcinogenic potential. The available dermal carcinogenicity studies do not definitively characterize the carcinogenicity of chlorine dioxide, and additional studies are required, and will be included in a data call-in (DCI) to follow this RED. One subchronic rat study, examined the effects of administration of chlorine dioxide at dose levels of 0, 25, 50, 100, or 200 mg/L for 90 days in drinking water. In this subchronic rat study, a significant increase in the incidence of nasal lesions was found at all dose levels tested. The significance of these findings is uncertain, as they have not been observed in other long-term studies of chlorine dioxide.

Mutagenicity

The Agency reviewed data from submitted studies as well as open literature. Data on the mutagenicity of chlorine dioxide indicate that negative effects were reported in one study from a 400-fold drinking water concentrate of chlorine dioxide, whereas a 4000-fold concentrate was mutagenic only in the absence of metabolic activation. In another study, chlorine dioxide was positive for forward mutations under non-activated conditions. Chlorine dioxide was positive for structural chromosome aberrations under non-activated and activated conditions and was negative for increased transformed foci up to cytotoxic levels. In one mouse study on chlorine dioxide, *In vivo* micronucleus and bone marrow chromosomal aberration assays were negative, as was a sperm-head abnormality assay.

Developmental/Reproductive

One developmental toxicity study conducted using rats was conducted for chlorine dioxide and sodium chlorite. In this study, a NOAEL of 20 mg/L was established based on decreased exploratory and locomotor activities in the offspring of rats exposed to chlorine dioxide in drinking water. Another developmental toxicity study conducted in rabbits using sodium chlorite established a NOAEL for developmental and maternal toxicity at 200 ppm, based on a dose-related increase of does with reduced fecal output during the dosing period, consistent with decreased food consumption.

A two-generational reproductive toxicity study was performed using sodium chlorite. The NOAEL for this study is 35 ppm (2.9 mg/kg-day) and the LOAEL is 70 ppm (5.9 mg/kg-day chlorite) based on lowered auditory startle amplitude and absolute brain weights in two generations. There were no significant effects of chlorine dioxide on body weight of dams or pups at any dose level tested.

Endocrine Disruption Potential

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

2. FQPA Safety Factor Considerations

The FQPA Safety Factor (as required by FQPA) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. For chlorine dioxide and sodium chlorite, the FQPA Safety Factor has been removed (i.e., reduced to 1X). This safety factor has been removed because the endpoint selected for both dietary and non-dietary exposures was based upon adverse effects observed in offspring from developmental and reproductive toxicity data. This approach is consistent with that used by the EPA's Office of Water for use of chlorine dioxide as a drinking water disinfectant (Federal Register Vol. 63, No. 61, pages 15673-15692, March 31, 1998) and the updated guidance on selection of a safety factor under FQPA. The endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide and sodium chlorite is believed to be protective of potentially susceptible populations, including children, based upon the selection of an endpoint and effects observed in offspring and the use of a NOAEL value based on those effects. Therefore, it was concluded that an additional safety factor under FQPA is not necessary in this case. Further, the risk assessment does not underestimate the potential exposure for infants and children.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for

the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

Acute dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose, modified by the FQPA safety factor. Although several studies were considered, an acute reference dose (aRfD) was not identified for chlorine dioxide. None of the available studies provided an endpoint of toxicity attributable to a single exposure. Therefore, no acute dietary endpoint for chlorine dioxide and sodium chlorite was selected.

b. Chronic PAD

Chronic dietary risk for chlorine dioxide is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose modified by the FQPA safety factor. The cPAD was derived from a two-generation reproduction toxicity study and a developmental toxicity study in which the NOAEL (3 mg/kg/day) and LOAEL (6 mg/kg/day) were determined. The chlorine dioxide and sodium chlorite cPAD is 0.03 mg/kg/day based on a reference does of 0.03 mg/kg/day, which incorporates the FQPA safety factor (1X) for the overall U.S. population and all population subgroups.

Metabolites and Degradates

Sodium chlorite is a strong oxidizing agent and under proper reducing conditions is readily reduced to chloride, and to a lesser extent, chlorate. In strong acidic conditions, chlorite can change into chlorine dioxide. The main source of chlorite ion exposure in the soil, water, or indirect food contacts is through the disinfectant applications. However, it is likely that some chlorate in these media is formed through use of antimicrobial applications (disinfectant) of chlorine dioxide, sodium chlorite, and sodium/calcium hypochlorites.

In aqueous media, these oxyanions (chlorite, chlorate, and hypochlorite) exist because of the unique chemistry of chlorine, that has a tendency to change its oxidation states (charges). Thus, in chlorate, chlorine has a +5 charge, in chlorite it bears a +3 charge, in hypochlorite a + 1 charge, while in chloride a net -1 charge exists. These variations in charges (hence the speciations) are dependent on factors such as: pH of the medium, temperature, redox potential of the medium, presence of oxidizing or reducing species, etc. Similarly, chlorate itself can undergo redox reactions, depending on the pH of the aqueous medium to form, chloride, chlorine, hypochlorite, chlorous acid, chlorine dioxide.

The Agency lacks data that would quantify the interconversions between chlorate, chlorine dioxide, sodium chlorite, and sodium/calcium hypochlorite. Simultaneous conversions of these species are not likely to occur as these factors (mentioned above) do not work in tandem.

Thus at this time, any additional dietary risks from interconversions in drinking water (non-cancer risks), and food (non-cancer risks) cannot be estimated. The Agency has included the highest possible dietary contribution of chlorite ion from use of sodium chlorate from the most sensitive subpopulation in the dietary risk estimates of sodium chlorite. Therefore, the Agency has conservatively determined that there are no additional risks other than the ones that have been estimated in chlorine dioxide/sodium chlorite Risk Assessment and sodium chlorate RED.

The inorganic chlorates were evaluated in the Inorganic Chlorates Reregistration Eligibility Decision (case number 4049) (hereinafter referred to as the "Inorganic Chlorates RED"). That assessment considered the contribution of chlorate ion from the use of chlorine dioxide and sodium chlorate. Please see *Revised Sodium Chlorite Risk Assessment,* dated July 27, 2006, for additional details.

4. Exposure Assumptions

The use of chlorine dioxide and sodium chlorite on food or feed contact surfaces, agricultural commodities, in animal premises and poultry premises including hatcheries and application to food-grade eggs may result in pesticide residues in human food. No residue chemistry data were required to support these uses in the past; therefore, no residue data was available for the assessment of these uses

To estimate chlorine dioxide residues on food due to migration of this chemical from sanitizing and/or disinfecting hard non-porous surfaces, the Agency has used the US Food and Drug Administration (FDA) model to determine the Estimated Daily Intake (EDI). Potential use sites include: (1) poultry hatcheries, (2) food handling establishments, (3) post-harvest potato treatments, (4) poultry house disinfection, poultry chiller water/carcass spray or dip, (5) food processing plants (meat and fish), (6) dairies, breweries, and bottling plants, and (7) pulp/paper, polymer slurries, paper adhesive, and paper coating. The EDI calculations presented in this assessment assumes that food can contact 2,000 cm^2 or 4,000 cm^2 (50% and 100% respectively of the FDA worst case scenario) of treated surfaces, and that 10% of the pesticide would migrate to food. The use of the 10% transfer rate, instead of the 100% transfer rate was used for all indirect food contact surfaces except for food bottling and packaging surfaces. The 10% migration rate is based on Agency Residential Standard Operation Procedures. These daily estimates were conservatively used to assess both acute (i.e. percent acute population adjusted dose or %aPAD) and chronic dietary risks (i.e. percent chronic population adjusted dose or %cPAD). The maximum application rate of 1000 ppm for chlorine dioxide from the various labeled products was used. Additional details about the dietary assessment can be found in "*Dietary Risk Assessment for Chlorine Dioxide and Sodium Chlorite Indoor Uses as Disinfectants/Sanitizers,*" dated July 22, 2006.

The Agency has conservatively added the highest chronic dietary exposure to chlorite ion from consumption of food treated with inorganic chlorates to the total chronic dietary exposure from chlorine dioxide/sodium chlorite. This assumes that all residues on food resulting from the use of inorganic chlorates are sodium chlorite. The Agency has decided to include these exposures as part of the chlorine dioxide/sodium chlorite dietary assessment in order to ensure

that the most conservative dietary assumptions are used. The inclusion of these exposures is considered to be highly conservative because it is unlikely that significant chlorite residues will result from the use of inorganic chlorates on food crops. As mentioned previously, the inorganic chlorates have been reassessed separately from chlorine dioxide.

There is no evidence that there will be residues of chlorine dioxide or sodium chlorite in mushrooms following its use as a mushroom house disinfectant. Further, if dietary exposures from mushroom house uses occurred they would be expected to be much lower than the dietary exposures resulting from the surface disinfectant and sanitizing uses. The labels associated with mushroom house use state that the product is not to be applied to the mushroom crop, compost or casing and that treated surfaces are to be rinsed with potable water before contact with the crop, compost or casing. Because any potential exposures would not likely pose risks of concern and the sanitizing uses represent a worst-case scenario, these uses were not assessed.

5. Dietary (Food) Risk Assessment

The Agency conducted a dietary exposure/risk assessment for chlorine dioxide and sodium chlorite. Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Table 3.

a. Acute Dietary Risk

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

b. Chronic Dietary Risk

A chronic dietary risk assessment was conducted for chlorine dioxide/sodium chlorite direct and indirect application to food. For indirect food applications, the highest individual subpopulation percent cPAD calculated is 4.2% for children's consumption of milk. For direct food uses, the chronic risk from the post-harvest use of fruit and vegetable washes is 42% of the cPAD for children. For the chlorite exposure resulting from the use of inorganic chlorate application to agricultural crops, exposure to children (most highly exposed subpopulation) resulted in risk estimate of 28 % of the cPAD. As a conservative measure, the dietary risk estimates of sodium chlorite include the highest dietary risk estimate for sodium chlorate for the most sensitive subpopulation.

Although there is not a concern for chronic dietary risk estimates alone, it is important to note that the individual exposure received from the post-harvest application of sodium chlorite to fruits and vegetables is an extremely high-end estimate. This assessment was conducted with the most conservative assumptions and resulted in an estimate of 42% of the cPAD for children ages 1-2. For example, this assessment assumed that all fruits and vegetables in the U.S. had a chlorine dioxide solution applied and that these commodities were not washed, cooked or processed prior to consumption. However, the Chlorine Dioxide Panel has agreed to limit the

residual concentration of chlorine dioxide to 3 ppm for post-harvest application to fruits and vegetables that are not Raw Agricultural Commodities. In order to get to this residual, the panel has agreed to label restrictions that require that fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce. Although the Agency cannot quantify the reduction of chlorine dioxide dietary exposure resulting from this mitigation measure at this time, it is believed that this measure would significantly reduce the percent of chlorine dioxide cPAD resulting from this use.

The dietary risks for adult and children from food uses are shown in Table 3. As there is no acute dietary endpoint for chlorine dioxide, only chronic dietary risk is presented. For adults, the total chronic dietary risk is 9.1% of the cPAD and is not of concern. For children (1–2 years), and infants less than 1 year old, the total dietary exposure is 76%, and 32% of the cPAD, respectively. These risks are below the Agency's level of concern, less than 100% of the cPAD. As stated above, this risk scenario is very conservative. For example, the Agency does not believe that 100% treatment of fruits and vegetables is a realistic scenario. If 50% of this food is treated, which we think is still unrealistic, the cPad for children (1-2 years) would be approximately 54%. The Agency will issue a DCI requiring data be submitted on how much food is washed with these pesticides.

Table 3. Summary of Dietary Exposure and Risk for Chlorine Dioxide					
Use Site	**Food Type**	**Population Subgroup**	**EDI (mg/person/day)**	**Chronic Dietary**	
				Dietary Exposure[a] (mg/kg/day)	**% cPAD [b]**
Indirect Food Use					
Food handling establishments/ kitchens	NA	Adult	2.00×10^{-1}	9.5E-07	0.00316
		Child		8.8E-06	0.0293
Dairies, Breweries, Bottling Plants, Food Contact Surfaces/Food Processing Plants for Meats and Fish[d]	Beverages, alcoholic, beer	Adult	1.2×10^{-3}	1.70E-05	0.56
	Beverages, non-alcoholic	Adult	1.6×10^{-3}	2.40E-05	0.08
		Child		1.00E-04	0.33
	Egg Products, Mayonnaise	Adult	1.4×10^{-4}	2.00E-06	0.0086
		Child		9.33E-06	0.031
	Milk	Adult	1.9×10^{-2}	2.70E-04	0.66
		Child		1.30E-03	4.2
Pulp/Paper, Polymer Slurries, Paper Adhesive, Paper Coating	NA	Adult	1.1×10^{-1}	9.8E-05	0.326
		Child		2.3E-04	0.766
Total Indirect Food-Contact Exposure		**Adult**	**3.3×10^{-1}**	**4.12E-04**	**1.64**
		Child 1-2 years	**2.7×10^{-1}**	**1.65E-03**	**5.35**
		Infant <1			**<5.35 [f]**
Direct Food Use					
Post Harvest Application	Fruit and Vegetable Wash	Adult		2.24E-03[c, e]	7.5
		Child		1.27E-02 [c, e]	42.3
Total Direct Food-Contact Exposure		**Adult**		**2.24E-03**	**7.5**
		Child 1-2 years		**1.27E-02**	**42.3[g]**
		Infant <1		**3.49E-03**	**11.6 [f]**
Inorganic Chlorate Use					
Highest Exposure from Agricultural Use		**Child 1 – 2 years**		**8.38E-03[c]**	**28**
		Infant <1 year		4.511E-03	**15 [f]**
Total Dietary Exposure					
Total Direct and Indirect Food-Contact Exposure		**Adult**		**2.65E-03**	**9.1**
		Child 1-2 years		**2.27E-02**	**75.7**
		Infant <1 year			**<31.95 [f]**

a-- For adults, acute and chronic exposure analysis is based on a body weight of 70 kg. For adult females, the body weight is 60 kg. For children, exposure is based on a body weight of 15 kg.
*b--%PAD = dietary exposure (mg/kg/day) * 100 / cPAD, where cPAD for adults and children = 0.03 mg/kg/day;*
c--children 1-2 years of age, adults 20-49 years of age
d--food processing plants for meats/fish have exposures which are similar to other food contact surfaces, exposure numbers not included for this scenario.
e-- includes all fruits and vegetables and apple and orange juices; assumes 100% of fruit is washed with chlorine dioxide.
f--Infants (<1 year) are included in this table for comparison purposes and were not added to the total dietary exposure as it was not the most highly exposed subpopulation.
g--Assuming 50% of fruits/vegetables are treated, the dietary risk for children (1 – 6) would represent 21% of the cPAD.

6. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and groundwater contamination. Chronic dietary (water only) risk assessments were conducted using DEEM-FCID™ Version 2.03 and drinking water consumption data from the USDA's CSFII from 1994-1996 and 1998. Exposures were single point estimates; no residue decline was utilized.

Chlorine dioxide is commonly used as an antimicrobial material preservative and for disinfecting non-porous surfaces indoors. These use patterns are not expected to result in surface or groundwater contamination. However, chlorine dioxide is commonly used for drinking water treatment. Therefore, the drinking water discussion will focus on the dietary risks that result from drinking water treatment.

In the U.S., there are two primary methods of drinking water treatment that do not involve filtration. The first method is the generation of chlorine dioxide. In the second method, either gaseous chlorine or hypochlorite is used to produce free chlorine. Except when gaseous chlorine is used, these methods produce chlorate as a disinfection byproduct (DBP). The American Water Works Association (AWWA) Disinfection Systems Committee tracks disinfection practices in US community water systems. AWWA's most recent comprehensive survey (completed in 1998) estimated that, of all community water systems (CWS), approximately 20% of CWSs serving populations greater than 10,000 use sodium hypochlorite (2% generated it on-site), 8% use chlorine dioxide, and <1% use calcium hypochlorite. For CWSs using groundwater and serving populations less than 10,000, the survey estimated that approximately 34% use sodium hypochlorite, none use chlorine dioxide, and at least 4.5% use calcium hypochlorite. For CWSs using surface water and serving less than 10,000, the survey estimated that 17% use sodium hypochlorite, 6% use chlorine dioxide, and 9% use calcium hypochlorite.

For chlorine dioxide generation, both sodium chlorate and sodium chlorite are used as precursor materials in the water disinfection process. Sodium chlorite is more commonly used than sodium chlorate. The free chlorine disinfection process involves the use of either gaseous chlorine, or sodium or calcium hypochlorite, as precursor materials. Historically, gaseous chlorine has been far more widely used than hypochlorite to produce free chlorine. In recent years, primarily as a result of various homeland security measures, many drinking water systems are switching from gaseous chlorine to hypochlorite. These processes (except for the use of gaseous chlorine) result in chlorate byproduct in finished drinking water, exposure to which was considered in the Inorganic Chlorates RED.

The chlorite ion (ClO_2^-) is a major degradation product resulting from the reaction of chlorine dioxide with inorganic and organic constituents in the water. When free chlorine is used after the application of chlorine dioxide in the treatment process, chlorite is oxidized to chlorate. This conversion will continue over time as the water travels through the distribution system. Chlorate ion is also formed by photodecomposition of chlorine dioxide when treated water is exposed to bright sunlight in open basins. The rate at which chlorate forms affects the amount of chlorine dioxide or chlorite that remain in the finished drinking water. Formation of chlorate from chlorite and chlorine dioxide was considered in the Inorganic Chlorates RED.

a. Drinking Water Exposure

Data on the occurrence of sodium chlorite in drinking water were available from the Information Collection Rule (ICR) Auxiliary 1 Database, Version 5.0. The water systems represented in the ICR database serve 60% of the total U.S. population. The EPA Office of Water (OW) issued the ICR in order to collect data to support future regulation of microbial contaminants, disinfectants, and disinfection byproducts. Monitoring for sodium chlorite was included in the ICR. Source water and drinking water were monitored for sodium chlorite ion between July 1997 and December 1998. Water systems serving a population of at least 100,000 were required to monitor for chlorite ion at treatment plants using chlorine dioxide or hypochlorite solutions in the treatment process. Plants using chlorine dioxide collected monthly samples of the source water entering the plant, the finished water leaving the plant, and at three sample points in the distribution system (near the first customer, an average residence time, and a maximum residence time). Plants using hypochlorite solutions were required to collect quarterly samples of the water entering and leaving the plant. If chlorine dioxide or hypochlorite solutions were used intermittently at a plant, chlorite ion samples were only required in sample periods in which they were in use.

Monitoring data were collected from 29 water treatment plants using chlorine dioxide treatment. The minimum reporting level (MRL) was established at 20 µg/L, all samples below this value were considered zero. Data from 418 samples (point of entry to the distribution) showed chlorite ion concentration ranged from 20 µg/L to 2,029 µg/L. Data from 1,115 samples (collected from within the distribution system) showed the concentration of chlorite ion between 20 µg/L to 1,850 µg/L. The average concentration of chlorite ion from 27 out of 29 treatment plants when averaged from the three distribution system sample points ranged from 20µg/L to 801 µg/L.

Based on the results of this monitoring data, the Agency established a maximum contaminant level goal (MCLG) and a maximum contaminant level (MCL) for chlorite ions. The MCLG and MCL are 0.8mg/L and 1.0 mg/L, respectively. In the original ICR monitoring data a number of samples and distribution systems showed large exceedences based on the MCL and MCLG. Currently, water systems have indicated that treatment is generally designed to meet a level of at least 20% below the MCL in order to ensure compliance. Based on this assumption, the Agency has readjusted all reported concentrations over 1000µg/L to 800 µg/L and recalculated the data. Table 4 below shows the adjusted values for chlorite concentrations.

Based on the values obtained from the monitoring data, the Agency conducted a drinking water assessment using chlorite concentrations at the maximum, 90th percentile, and median annual averages of chlorite concentrations of 0.7, 0.63, and 0.39 mg/L, respectively. The 90th percentile exposure values will be used in the aggregate risk assessments, with children represented by the 1-6 year old age category.

Table 4. Chlorine Dioxide Water Monitoring Data (μg/L) – ICR Data[a]

	Distribution System Entry Point	Near First Customer	Average Residence Time	Maximum Residence Time	Distribution System Average[2]
10th Percentile	60	52	58	30	45
20th Percentile	99	79	87	81	84
50th Percentile	440	380	360	310	390
80th Percentile	590	580	600	510	550
90th Percentile	660	660	640	650	630
Maximum	800	740	680	680	700
Number of Water Treatment Plants	29	27	27	27	27
Number of Public Water Systems	22	21	21	21	21

[a]ICR Data Adjusted for MCL Compliance

b. Acute Dietary Risk (Drinking Water)

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

c. Chronic Dietary Risk (Drinking Water)

The chronic dietary (water only) risk assessment for sodium chlorite in drinking water estimated at 49 % of the cPAD for the general U.S. population and is below 100% of the cPAD, and therefore, is below the Agency's level of concern. All risks for the U.S. population subgroups are below 100 % of the cPAD except infants (<1 year of age). The highest exposed subgroup, infants, was 161% of the cPAD, based on the highest annual average concentration of sodium chlorite, and therefore, above the Agency's level of concern. The 90th percentile exposure values will be used in the aggregate risk assessments, with children represented by the 1-6 year old age category. See Table 5 below for details.

Table 5. Chlorite Exposure by Population Group						
Population subgroup	**Maximum Concentration**		**90th Percentile Concentration**		**Median Concentration**	
	Total exposure (mg/kg/day)	**% cPAD**	**Total exposure (mg/kg/day)**	**% cPAD**	**Total exposure (mg/kg/day)**	**% cPAD**
U.S. Population	0.014754	49	0.013279	44	0.008220	27
Infants < 1 year	0.048372	161	0.043535	145	0.026950	90
Children 1-6 years	0.020613	69	0.018552	62	0.011485	38
Children 7 -12 years	0.013402	45	0.012062	40	0.007467	25
Females 13-50	0.014274	48	0.012846	43	0.007952	27

7. Residential Exposure

Residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Residential exposure may occur during cleaning or mopping of hard surfaces, application of chlorine dioxide to swimming pools and spas and through application to HVAC systems. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL. Based on its use pattern, the residential handler assessment evaluated application of chlorine dioxide-containing products by homeowners to control mold and mildew. The post-application assessment evaluated risks from dermal, inhalation and incidental oral exposure for children due to hand-to-mouth exchange.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for chlorine dioxide and sodium chlorite are listed in Table 6.

A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the dermal, incidental oral and inhalation routes of exposure. The MOE of 100 includes 10x for inter-species extrapolation, 10x for intra-species variation.

Table 6. Summary of Toxicological Doses and Endpoint Selection for the Chlorine Dioxide/ Sodium Chlorite Residential Assessment			
Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	UF/MOE for Risk Assessment	Study and Toxicological Effects
Incidental Oral (short and intermediate term)	NOAEL = 3 mg/kg/day	MOE = 100	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups at LOAEL of 14 mg/kg/day
Dermal All Durations (1-30 days)	NOAEL = 3 mg/kg/day	MOE = 100	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups at LOAEL of 14 mg/kg/day
Inhalation (occupational and homeowner short-term)	Homeowner short-term: LOAEL = 28 mg/m^3 (10 ppm) Occupational exposure: LOAEL = 2.8 mg/m^3 (1.0 ppm) NOAEL = 0.28 mg/m^3 (0.1 ppm).	Homeowner short-term 'RfC' = **0.14 mg/m^3** (0.05 ppm) Occupational 'RfC' = **0.009 mg/m^3** (0.003 ppm)	Inhalation toxicity studies- Rat Dalhamn, 1957; Paulet and Debrousses, 1970, 1972.
Inhalation (homeowner long-term)	Agency RfC methodology used to derive an RfC value of 2 x 10^{-4} mg/m^3 (USEPA, 2000a)		(Paulet and Desbrousses, 1970, 1972) selected as co-critical studies (USEPA, 2000a)

b. Residential Handler

i. Exposure Scenarios, Data and Assumptions

Residential exposure to chlorine dioxide can occur through mopping, spraying, and applying products to pools and spas. A number of assumptions, or estimates, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment. In addition, for residential handlers it is assumed that all exposures are short-term.

The residential handler risk assessment based on these scenarios:
(1) Mopping: 1 gal/use
(2) Trigger-pump sprayers: 0.5 liters or 0.13 gal/day
(3) Swimming pools: 160 g ai/20,000 gallons of water

Chlorine dioxide and sodium chlorite products are widely used and have a large number of use patterns that are difficult to completely capture in the risk assessment. As such, the Agency has selected representative scenarios for each use site that are believed to be high-end estimates for the vast majority of chlorine dioxide uses, based on end-use product application methods and use amounts.

For the residential handler risk assessment, dermal unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study, 1999, (MRID 42587501) or from the Pesticide Handler Exposure Database (PHED, 1998). The scenarios evaluated for dermal and inhalation risks in the residential handler assessment are as listed below:

- Mopping floors;
- Applying trigger-pump sprays to hard surfaces; and
- Placing solid tablets in swimming pools or spas
- Off-gassing during application of the aqueous solution.

The potential exposures from mopping and cleaning are expected to be best represented by the short-term duration. Dermal and inhalation exposures were assessed for all residential handler scenarios. For the mopping application and application of tablets to swimming pools and spas, values from the Chemical Manufacturers Association (CMA) antimicrobial study (U.S. EPA, 1999) were used. For the application of chlorine dioxide products with a trigger-pump spray, the Pesticide Handler Exposure Database (PHED, 1998) was used to determine exposure. To determine the potential inhalation handler exposure resulting from the vapor of chlorine dioxide as a general purpose cleaner, the model EFAST (Exposure and Fate Assessment Screening Tool) was used to estimate the chlorine dioxide air concentrations. For additional information, please refer to "Chlorine Dioxide Occupational and Residential Exposure Assessment," dated August 2, 2006.

ii. **Residential Handler Risk Estimates**

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. A summary of the residential handler exposures and risk are presented on Table 7. The exposure duration of most homeowner applications of cleaning products and pools are believed to be best represented by the short-term duration. The toxicological endpoint is based on an oral study and no dermal absorption value is available. Therefore 100% dermal absorption was assumed for chlorine dioxide or chlorite ion residues. While there is some evidence that chlorine dioxide is readily absorbed in skin, this assessment is very conservative. The dermal MOEs for the floor mopping, and application to hard surfaces, are above the target MOE of 100, and therefore, are not of concern. The short-term dermal MOE for pool or spa treatments is 46 without the use of gloves and is of concern to the Agency; therefore, the labels must be amended to require gloves. Based on the average daily air concentration, the handler inhalation exposures of chlorine dioxide are not of concern (i.e., the average air concentration estimated by EFAST of 0.003 ppm is below the RfC of 0.05 ppm).

Table 7. Calculation of Short-term Dermal MOEs for Residential Handlers

Exposure Scenario		Application Rate[a] (lb ai/gal)	Amount Handled/ Treated Daily[b] (gal)	Baseline Dermal Unit Exposure[c] (mg/lb ai)	Baseline Dermal Dose[d,e] (mg/kg/day)	Baseline Dermal MOE[f] (Target MOE = 100)
Mopping (CMA data)	Hard Surfaces	0.002	1	71.6	0.0024	1300
Trigger-pump sprayer (Aerosol can PHED data used as surrogate)	Hard Surfaces	0.002	0.13	220	0.00095	3200
Solid Place (Tablets)	Pools & Spa water Circulation Systems	1.8E-5 (4 tablets /10,000 gal. Pool tablet is 100 g x 4 tablets x 20%ai = 80 g ai/10,000 gal = 1.8E-5 lb ai/gal)	20,000 gal	10.8 (no gloves)	0.065 (no gloves)	46 (no gloves)
				0.412 (with gloves)	0.006 (with gloves)	500 (with gloves)

c. Residential Post-Application

i. Exposure Scenarios, Data and Assumptions

Residential post-application exposures result when bystanders (adults and children) come in contact with chlorine dioxide in areas where pesticide end-use products have recently been applied (e.g., treated hard surfaces/floors), or when children incidentally ingest the pesticide residues through hand-to-mouth contact of the treated surface. The residential post-application scenarios considered in this assessment are exposure to residues from hard surfaces (i.e., floors) that have been mopped or cleaned with a product containing chlorine dioxide, the use of continuous release air deodorizers, and a single treatment of HVAC systems with chlorine dioxide.

Chlorine dioxide and/or sodium chlorite can be applied as an aqueous solution to hard surfaces such as floors and potentially result in inhalation exposure. The Agency assessed these risks based on dilution and ventilation along with the half-life of chlorine dioxide. This assessment estimated an 8-hour time weighted average air concentration starting immediately after application.

Typically, most products used in a residential setting result in exposures occurring over short-term time duration (1 – 30 days). For the purposes of this screening-level assessment, post application scenarios have been developed that encompass multiple products, but still represent a high-end scenario for all products represented.

Four scenarios have been evaluated in the residential post-application assessment.

1. Exposure to residue from hard floors that have been cleaned with a solution containing chlorine dioxide;
2. Exposure to chlorine dioxide used to clean residential HVAC systems;
3. Exposure to a continuous release (gas) deodorizer; and
4. Swimming in treated pools or spas.

ii. Residential Post-Application Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal, incidental oral and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 100 are considered adequately protective for the residential exposure assessment.

A summary of the residential handler exposures and risk are presented on Table 8. The risks from dermal and incidental oral exposures for all scenarios are below the Agency's level of concern.

For children, the short- and intermediate-term oral and dermal MOEs for contact of hard surfaces following disinfection are above the target MOE of 100 for applications in residential and daycare settings. Therefore, the risks from these uses are not of concern.

Inhalation exposures due to post application activities could occur for children after the treatment of floors; adults and children after the treatment of HVAC systems; and adults and children after the use of continuous release (gas) deodorizers. Chlorine dioxide/sodium chlorite can be applied as an aqueous solution to hard surfaces such as floors and potentially result in inhalation exposure. For this assessment, the Agency estimated the air concentration to be 0.003 ppm, which is below the short-term RfC of 0.05 ppm, and therefore not of concern. For application to HVAC systems, this use is not of concern. For the continuous release deodorizer, the estimated constant air concentration was 0.52 ppm, assuming no air exchange and no build up of chlorine dioxide over time because of the short half-life. This risk is of concern to the Agency. The RfC for long-term continuous exposure is 0.00007 ppm; therefore this risk is of concern to the Agency. The registrant has agreed to delete residential uses of these products.

The application of chlorine dioxide to swimming pools or spas, is not assessed quantitatively. Based on use directions on current labels, dermal, incidental oral, and inhalation exposures to chlorine dioxide residual levels after the dilution in the water, and cleaning of the circulation systems are expected to be minimal. Table 8 shows a representative sample of the short- and intermediate-term residential post-application risks.

There is also the potential for inhalation exposure as a result of the use of chlorine dioxide as a dust on carpets. The registrant has agreed to mitigate any potential risk from this use by limiting it to professional carpet applicators, packaging only in containers that are large enough to discourage retail sale and requiring an REI of one hour prior to entry into a treated room.

Table 8. Summary of Short- and Intermediate-Term Residential Post-application Exposures and Risks

Scenario		Dose [a] (mg/kg/day)	MOE[b]
Dermal Exposure			
Hard surface Disinfection	Residential Setting and Daycare Center	0.017 [a]	280
Incidental Oral Exposure			
Hard surface Disinfection	Residential Setting and Daycare Center	0.0013[a]	2,300

Inhalation Exposure			
Scenario		Estimated Air Concentration	RfC (level of concern)
Application to HVAC Systems	Residential Setting and Daycare Center	<0.01 ppm	0.05 ppm [c]
Continuous Release Deodorizer	Residential Setting and Daycare Center	<0.52 ppm	0.00007 ppm [d]

[a] Dose calculations for each scenario above are outlined in the attached Occupational/Residential Assessment.
[b] MOE= NOAEL (mg/kg/day) / Dose (mg/kg/day). Oral and dermal NOAEL is 3 mg/kg/day.
[c] RfC - short-term target is 0.05 ppm.
[d] RfC - long-term target is 0.00007 ppm.

8. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and if applicable, residential or other non-occupational exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. Aggregate exposure and risk assessments for sodium chlorite include the following: food + water + residential handler. For the aggregate of the inhalation route of exposure, only use of the continuous release air deodorizer product is assumed to co-occur with the other uses. In addition, the HVAC applications will not occur frequently (single exposure); therefore it was not included in the aggregate assessment. The inhalation risk for the continuous release is of concern by itself. Because we have agreement that the residential application of the continuous release deodorizer will be canceled, it has been removed from consideration in the aggregate assessment. However, the continuous release air deodorizer will be allowed in spaces where extended exposure is not likely, e.g., dumpsters. This mitigation will result in aggregate risks that are no longer a concern. Results of the aggregate risk assessment are summarized here, and are discussed more extensively in the document: *Revised Chlorine Dioxide Risk Assessment,* dated July 27, 2006, which is available in the public docket.

a. Acute Aggregate Risk

For chlorine dioxide, the acute and chronic aggregate risk assessments include only dietary, drinking water, and residential exposures. An acute dietary risk assessment was not conducted for chlorine dioxide because there were no acute dietary endpoints of concern.

b. Short- and Intermediate -Term Aggregate Risk

The short- and intermediate-term aggregate assessments were conducted for adults and children. Table 9 shows the exposure scenarios that were included in the aggregate assessment for chlorine dioxide. Use patterns involving exposure by inhalation (continuous use deodorizer) were not aggregated because these use patterns were above the Agency's level of concern on their own and the Agency has agreement that the use will be voluntarily cancelled, therefore these aggregate risks are no longer a concern.

Table 9. Exposure Scenarios Included in the Aggregate Assessments

	Short-term Aggregate	Intermediate-Term Aggregate
Adults	▪ chronic dietary (direct and indirect) ▪ handling cleaning products – spray (dermal only) ▪ handling cleaning products – mopping (dermal only) ▪ chronic drinking water	Not Assessed
Children	▪ chronic dietary – (direct and indirect) ▪ post-app to cleaning product (dermal and oral) ▪ chronic drinking water	▪ chronic dietary – (direct and indirect) ▪ post application to cleaning product (dermal and oral) ▪ chronic drinking water

a Dietary (indirect + direct food contact) exposures = sum of dietary exposures presented in Table 3.
b Aggregate Dietary Exposures = sum of both dietary (direct and indirect food contact) exposures and drinking water exposures.

The toxicity endpoints for the oral and dermal routes of exposure are based on the same study and same toxic effect; therefore, these two routes of exposure are aggregated together. Table 10 presents a summary of these exposures, including the aggregate dietary exposure (all direct and indirect food contact exposures) as well as a total dietary aggregate exposure value (drinking water plus direct/indirect dietary exposures). Table 10 presents a summary of the short- and intermediate-term aggregate exposures and the corresponding aggregate risks.

The short-term and immediate-term aggregate risks are not of concern for adults (total MOE=130). The short-term and immediate-term aggregate risks are of concern for children (MOE=44) and infants (MOE=41). The primary driver for these risks is dietary exposures.

Table 10. Short- and Intermediate-term Aggregate Risks (MOEs)					
Exposure Routes	Aggregate Dietary Risks	Dermal Risks (MOE)			Aggregate Risks (MOE)
		Hard Surface Cleaning			
		Applicator		Post-Application	
		Mop	Spray		
Adults					
Oral Ingestion MOEs	150	NA	NA	NA	150
Dermal MOEs	NA	1300	3200	NA	900
Total MOE	150	1300	3200	NA	130
Children (age 1 – 6)					
Oral Ingestion MOEs	60	NA	NA	2300	58
Dermal MOEs	NA	NA	NA	180	180
Total MOE	60	NA	NA	160	44
Infants < 1					
Oral Ingestion	55	NA	NA	2300	55
Dermal MOEs	NA	NA	NA	180	180
Total MOE	55	NA	NA	160	41

MOE = NOAEL/dose
Aggregate MOE = $1/((1/MOE_{dietary}) + (1/_{MOEdrinking\ water}) + (1/MOE_{dermal})$
All NOAELs = 3 mg/kg/day
Target MOE oral = 100
Target MOE dermal = 100

c. Chronic Aggregate Risk

The chronic aggregate risk estimates associated with chlorine dioxide from dietary uses are below the Agency's level of concern for adults at 53% of the cPAD. However the dietary risks are above the level of concern for children aged 1 to 6 (133% of the cPAD).

The chronic aggregate risks are not of concern for adults, as the total aggregate of the cPAD is 53% (excluding the continuous use deodorizer), below the target of 100%. For children, the aggregate risk estimates are above 100% (133% cPAD) and thus are of concern. Table 11 presents the chronic aggregate exposures and risks.

Table 11. Chlorine Dioxide Chronic Aggregate Exposures and Risks				
Exposure Routes	Chronic Dietary Exposures (mg/kg/day)			
	Dietary (indirect + direct food contact+ chlorate) Exposures[a]	Drinking water exposures	Aggregate Dietary Exposures[b]	Aggregate Dietary Risks (%cPAD)
Adults				
Oral Ingestion	2.65E-03	1.33E-02	1.6E-02	53.3%
Children (age 1 – 6)				
Oral Ingestion	2.27E-02	1.86E-02	4.13e-02	133%

a Dietary (indirect + direct food contact) exposures = sum of dietary exposures presented in Table 6.
b Aggregate Dietary Exposures = sum of both dietary (direct and indirect food contact) exposures and drinking water exposures.

9. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of chlorine dioxide and sodium chlorite include workers in a variety of occupational settings. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected for assessment were evaluated using maximum application rates as recommended on the product labels for chlorine dioxide and sodium chlorite.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose.

Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of chlorine dioxide and sodium chlorite, MOEs greater than 100 for dermal exposures and inhalation exposures are not of concern to the Agency. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

For more information on the assumptions and calculations of potential risk of chlorine dioxide to workers, see the Occupational Exposure Assessment section in the "Chlorine Dioxide Risk Assessment," dated July 27, 2006.

a. Occupational Toxicity

Table 6 provides a listing of the toxicological endpoints used in the occupational risk assessment for chlorine dioxide and sodium chlorite.

b. Occupational Handler Exposure

Potential occupational handler exposure can occur at various use sites, including agricultural, food handling, commercial and institutional, and medical premises; human drinking water systems; industrial processes and water systems; application to materials as preservatives; and swimming pools and other aquatic areas.

The Agency has assessed the handler risks from the use of chlorine dioxide using unit exposure data from both the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). Table 12 lists the handler exposure scenarios assessed for chlorine dioxide. These scenarios are considered representative of high-end exposures for the industrial applications.

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document

Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Use Site Category I (Agricultural Premises and Equipment)[a]				
Application to Hard Surfaces and Equipment	low-pressure hand wand	74602-2 (Sodium Chlorite)	(Application rate from label, 2.5 fl oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.015	Short- and Intermediate-term (ST and IT) Adult Handler (dermal and inhalation) and Adult Bystander and Post Application (dermal and inhalation)
	trigger-pump sprayer fogger (1 hour REI after fogging)	74602-2 (Sodium Chlorite)	(Application rate from label, 2.5 fl oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.015	
	mop	9150-2 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.69 lb ai/gal) = 0.018	

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
	foaming wand	9150-11 (Chlorine Dioxide)	(Application rate from label, 0.25 gal of product*0.10 lb ai/gal) = 0.025 lb ai/gal.) Apply at rate of 4 to 6 gallons/minute to inside/outside of animal trucks/equipment.	
	ULV fogger (e.g., Dramm fogger)	74602-2 (Sodium Chlorite)	(Egg house label rate, 1 gal product x 5% ClO2) per 50 gal = 0.0083)	
Use Site Categories II (Food Handling), III (Commercial/Institutional), and V (Medical)				
Application to Hard Surfaces and Equipment Without Food Contact	mop	9150-10 active (10589-3 transferred) (Chlorine Dioxide)	(Application rate from label, 5 oz/gal)*(1 gal/128 oz)*(0.49 lb ai/gal) = 0.019	ST/IT Adult Handler (dermal and inhalation) and Adult Post Application/Bystander (dermal and inhalation)
	trigger-pump sprayer	21164-3 (Sodium Chlorite)	(Application rate from label, 12 fl oz/gal)*(1 gal/128 oz)*(0.86 lb ai/gal) = 0.08	
Application to foods (Fruit/Vegetable Rinse)	dip	74602-2 (Sodium Chlorite)	(Application rate from label, 1.9 oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.011	
Use Site Category VI (Human Drinking Water Systems)				
Application to Water Systems (Water Treatment and Water Storage Systems)	metering pump	9804-1 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.27 lb ai/gal) = 0.007	ST/IT Adult Handler; Potential for inhalation exposure unknown at this time.

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Use Site Category VII (Material Preservatives)				
Applications to Metal Working Fluids	liquid pour	9150-2 (Chlorine Dioxide)	batch method: 0.0001 (per week) continuous method: 8E-7 (per day) badly contaminated systems: 4E-6 (slug dose)	ST/IT Adult Handler (dermal and inhalation) and Long-term Dermal and Inhalation for Machinists.
Use Site Category VIII (Industrial Processes and Water Systems)				
Application to Pulp and Paper White Water Systems	metering pump	74602-3 (Sodium Chlorite)	(Application rate from label, 15 gal/100,000 gal white water to be treated or 4 gal/100 tons paper produced)*(0.86 lb ai/gal) = 0.0001 lb ai/gal white water or 3.44 lb ai/100 ton paper produced	ST/IT Adult Handler (dermal and inhalation) and Adult Bystander (inhalation)

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Application to Oil Systems (oil Wells During Secondary Recovery Operations)	liquid pour	9150-2 (Chlorine Dioxide)	(Application rate from label, 1 gal/10 gal)*(0.69 lb ai/gal) = 0.069. Label indicates to portion 1 part of this solution to 150 parts reinjection water.	ST/IT Adult Handler (dermal and inhalation) and Adult Bystander (inhalation)
Use Site Category XI (Swimming Pools)				
Application to Public Swimming Pool Circulation Water Systems (Swimming Pools)	solid place (tablets)	70060-20 (Sodium chlorite)	4 tablet /10,000 gal (Pool tablet is 100 g x 4 tablets x 20%ai = 80 g ai/10,000 gal = 1.8E-5 lb ai/gal)	Short-term Adult Handler (dermal and inhalation)
Use Site Category XII (Aquatic Areas)				
Non-potable Water Systems (e.g., retention basins and ponds, decorative pools and fountains)	liquid pour	9150-11 (Chlorine Dioxide)	0.00001 (18 fl oz x 0.72% ai per 100 gallons water)	ST/IT Adult Handler (dermal and inhalation)
Use Site Category XIII (HVAC)				

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Application to Ventilation Systems (HVAC)	airless sprayer fogger (1hour REI after fogging)	9804-1 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.27 lb ai/gal) = 0.007	ST/IT Adult Handler (dermal and inhalation) and Short-term Child and Adult Post Application (inhalation)

c. Occupational Handler Risk Summary

i. Dermal Risks

For the occupational handler dermal risk assessment, the short- and intermediate- term risks calculated at baseline exposure (no gloves and no respirators) were above target MOEs for all scenarios (i.e., dermal MOEs were >100), except for the following:

Agricultural premises and equipment:

- application to hard surfaces: low pressure handwand (MOE=31);
- application to hard surfaces: mopping (MOE=70); and
- application to hard surfaces: foam applicator equipment (MOE=8).

Food Handling, Commercial/Institutional, and Medical Premises and Equipment:
application to hard surfaces:

- mopping (MOE=66 commercial; 3 medical).

Swimming pools:

- placement of tablets (MOE=5)

A summary of the occupational handler assessment is provided in Table 13.

Table 13. Short-, Intermediate-Term Dermal Risks for Occupational Handlers					
Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	Dermal MOE[c]	
				Baseline Dermal[a] (Target MOE>100)	PPE Gloves Dermal[b] (Target MOE>100)
1Agricultural Premises and Equipment					
Application to Hard Surfaces	Low pressure handwand	0.015	2	**31**	No data
	Liquid Pour		0.188	1,300	6,300
	Trigger-pump sprayer		0.26	240	570
	Mopping	0.018	2	**70**	No data
	Foam applicator equipment	0.025	60	**3**	**8**
Food Handling, Commercial/Institutional, and Medical Premises and Equipment					
Application to Hard Surfaces	Mopping (general)	0.019	2	**66**	No data
	Trigger-pump sprayer	0.08	0.26	**46**	110
	Mopping (medical)	0.019	45	**3**	No data
Human Drinking Water Systems					
Water and Storage Systems	Metering pump	0.007	34,000	No data	120
Material Preservatives					
Metal Working Fluid	Liquid pour	0.0001	300	No data	33,000
Industrial Processes and Water Systems					
Paper and Pulp White Water Systems	Metering pump	0.0344 lb ai/ton paper	500 tons paper	No data	2,300
Oil Systems	Open pour	0.069	2.8	NA	6,900

Table 13. Short-, Intermediate-Term Dermal Risks for Occupational Handlers					
Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	Dermal MOE[c]	
				Baseline Dermal[a] (Target MOE>100)	PPE Gloves Dermal[b] (Target MOE>100)
			5.6		3,500
Swimming Pools and Aquatic Areas					
Retention Ponds/ Fountain	Liquid pour	0.00001	10,000 gal	No data	670
Swimming Pools (public)	Solid place	1.8E-5	200,000 gal	**5**	120
HVAC Systems					
HVAC	Airless sprayer	0.007	5	140	NA
	Fogger (liquid pour)		0.25	2,000	NA

a Baseline Dermal: Long-sleeve shirt, long pants, no gloves.
b PPE Dermal with gloves: baseline dermal plus chemical-resistant gloves.
c MOE = NOAEL (mg/kg/day) / Daily Dose [Where short-and intermediate-term NOAEL = 3 mg/kg/day for dermal exposure]. Target MOE is 100 for dermal exposure.

ii. Inhalation Risks

Inhalation exposures and risks were not assessed separately for the handlers. Instead, the occupational inhalation handler exposures are combined as part of the full work-day for handler/bystanders to be comparable to EPA's inhalation toxicological endpoint which is based on an 8-hour time-weighted average. For the peak, short-term exposures to chlorine dioxide gas experienced during mixing/loading and/or system leaks/failures, EPA will rely on the American Conference of Governmental Industrial Hygienists (ACGIH) Short-term Exposure Limit (STEL) and Immediately Dangerous to Life or Health (IDLH) standards to mitigate risks.

For most of the bystander/post application occupational scenarios, the inhalation risks for the bystander/post application occupational exposures are of concern using the EPA's selected inhalation toxicological endpoint (RfC). The occupational RfC, 0.003 ppm, is below the limit of detection for chlorine dioxide. Based on OSHA's Integrated Management Information System (IMIS) data available for chlorine dioxide, all air concentration measurements, even those that were undetectable, are above the RfC. EPA is aware of the discrepancy between the EPA risk-based RfC and current OSHA standards, reconciliation will occur at a later date.

d. Occupational Post-application

i. Dermal Post-Application Exposure

No information is available to assess post application/bystander dermal exposure to uses in agricultural premises as well as food handling, commercial/institutional and medical premises; human drinking water facilities; industrial processes; and retention ponds. However, dermal post application exposure to chlorine dioxide is expected to be less than that of the dermal contact of children playing on treated floor surfaces. Therefore, the dermal exposure route is not believed to be of concern in these industries.

ii. Inhalation Post-Application Exposure

Non-Fogging Uses

Post-application/bystander inhalation exposures were assessed by obtaining air concentration measurements from the Occupational Safety and Health Administration (OSHA) for the non-fogging uses. The data selected for this analysis include only those samples that are reported as 8-hour time-weighted average (TWA) measurements from personal air samplers. Other samples, such as peak concentrations and/or area monitors, have been omitted. The inhalation endpoint selected by EPA is 0.003 ppm, just below the OSHA LOD for an 8-hour TWA air sample. The summary results of the 33 observations taken from 8-hour TWA personal air samplers for chlorine dioxide are above the EPA selected inhalation reference concentration (RfC) of 0.003 ppm, and therefore, are of concern.

Fogging Uses

The fogging use of chlorine dioxide is unique such that no persons are present during the actual application/fogging. There is also a greater potential for chlorine dioxide gas formation from fogging than an aqueous-based application such as mopping. Therefore, a separate assessment was developed for foggers that indicate potential inhalation exposure and reentry recommendations. The air concentration in a fogged area should be below the occupational RfC of 0.003 ppm before the room is entered by persons not wearing respiratory protection.

One scenario based on labeled application rates allows chlorine dioxide fogging and misting applications while workers are in the room if the level of chlorine dioxide does not exceed the TLV-TWA of 0.1 ppm. The occupational RfC of 0.003 ppm could be exceeded based on these use directions (i.e., workers do not need to leave treatment area unless the TLV-TWA of 0.1 ppm is exceeded). This scenario is of potential concern to the Agency. To mitigate this risk, labels must be changed to prohibit re-entry into treated areas for one hour after treatment.

EPA's Risk-based RfC versus OSHA PEL

It is also important to note that the OSHA Permissible Exposure Limit (PEL) for chlorine dioxide is 0.1 ppm. Air concentrations above the PEL are assumed to be mitigated at each facility. Facilities using chlorine dioxide are not required to mitigate inhalation exposures until the air concentration reaches 0.1 ppm. Based on the occupational inhalation toxicological endpoint selected for chlorine dioxide (i.e., RfC of 0.003 ppm), levels at or near the PEL are of concern. In fact, the capability (i.e., LOD) of the OSHA sampling method is insufficient for the occupational RfC presented in this document. Reconciliation of the EPA risk-based RfC and the current OSHA standards will be made at a later date.

e. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to chlorine dioxide/sodium chlorite. EPA consulted the following sources of information for human poisoning incidents related to TCMTB use: **(1) OPP Incident Data System (IDS)** - The Office of Pesticide Programs (OPP) **Incident Data System** contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) **California Department of Pesticide Regulation (1982-2004)** – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982. (3) **National Pesticide Information Center (NPIC)** - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991.

There are some reported incidents associated with exposure to end-use products containing chlorine dioxide. Inhalation is the primary route of exposure. Most of the incidents are related to irritation type reactions to bronchial and nasal passages, and the eyes.

The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms, and headache.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for chlorine dioxide and sodium chlorite use sites and any associated uncertainties.

For a detailed discussion of all aspects of the environmental risk assessment, see the document "**Environmental Hazard and Risk Assessment**," dated July 13, 2006.

1. Environmental Fate and Transport

In the environment, chlorine dioxide and sodium chlorite are assessed together because chlorine dioxide is produced by a reaction of sodium chlorite (and sometime sodium chlorate) and hypochlorite/acid. In addition, chlorite is a breakdown product of chlorine dioxide.

Chlorine dioxide has a short half-life and in the presence of sunlight will break down into chloride and chlorate ions (between pH 4 and 7). At pH lower than 4, its breakdown products are chlorite and chlorate. Chlorite is the dominant breakdown product.

Chlorate and chlorite ions tend to only undergo biodegradation only under anaerobic conditions. Biodegradation of chlorate and chlorite has been observed in anoxic groundwater, sediments and some soils. The end products are the chloride and oxygen. No adsorption/desorption constants (K_ds) have been measured or reported in published literature for either chlorite or chlorate. These ions are likely to be mobile and may travel from surface to groundwater easily. The estimated log K_{ow} of chlorine dioxide is -3.22 and for sodium chlorite is -7.17. It is not expected that either would bioaccumulate in aquatic organisms.

2. Ecological Exposure and Risk

Chlorine dioxide and sodium chlorite are used as antimicrobial pesticides at numerous use sites. Sodium chlorite is used as a precursor in the generation of chlorine dioxide. The antimicrobial registered uses of chlorine dioxide/sodium chlorite fall into several major categories including use in the treatment of human drinking water systems; in industrial process and water systems; as a materials preservative; and as a general disinfectant in medical, residential, agricultural, commercial and industrial settings. The indoor uses of sodium chlorite will not result in exposure to the environment.

The use of chlorine dioxide in cooling towers was modeled because it represents the worst-case scenario for the chlorine dioxide uses. For terrestrial animals, the results of studies show that toxicity of chlorine dioxide/sodium chlorite to birds ranges from highly to slightly toxic to birds on an acute oral basis and from slightly toxic to practically non-toxic on a subacute dietary basis.

For freshwater aquatic animals, the results of studies examining the toxicity of chlorine dioxide/sodium chlorite to freshwater fish indicate these chemicals range from slightly toxic to practically non-toxic on an acute basis. For aquatic invertebrates, the studies indicate that chlorine dioxide and sodium chlorite range from very highly toxic for technical grade sodium chlorite to practically non-toxic for the formulated product on an acute basis. Results of toxicity studies indicate that chlorine dioxide/sodium chlorite are slightly toxic to estuarine/marine fish on an acute basis and range from highly toxic to slightly toxic to estuarine/marine invertebrates on an acute basis.

For terrestrial plants, results of toxicity studies indicate that chlorine dioxide/sodium chlorite are moderately toxic to terrestrial plants. For aquatic plants, toxicity study results

indicate chlorine dioxide/sodium chlorite are moderately toxic to aquatic plants.

For aquatic organisms, acute risk is anticipated from the use of chlorine dioxide/sodium chlorite in once-through cooling towers based on the modeling conducted. At the highest doses, there is risk to freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates. Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described above is submitted, chronic risk to these organisms will be assessed.

The once-through cooling tower use of chlorine dioxide/sodium chlorite has been selected for risk assessment because out of all the uses of these chemicals, it is the one expected to have the most potential for environmental exposure. The environmental risk assessment was conducted using sodium chlorite endpoints because under environmental conditions, chlorine dioxide converts mostly into chlorite ions.

3. Listed Species Consideration

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA, 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

Acute risk to listed birds and mammals is not anticipated from the use of chlorine dioxide and sodium chlorite products due to low exposure and low toxicity. Further evaluation is needed before it can be determined if there are risks to listed aquatic organisms from the once through cooling tower use of chlorine dioxide/sodium chlorite. Chronic risks to listed aquatic organisms cannot be assessed at this time; this risk will be assessed when required chronic toxicity data are submitted to and evaluated by the Agency. These conclusions are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing chlorine dioxide and sodium chlorite as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing chlorine dioxide and sodium chlorite.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient chlorine dioxide and sodium chlorite. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient chlorine dioxide and sodium chlorite, the Agency has sufficient information on the human health and ecological effects of chlorine dioxide and sodium chlorite to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that all chlorine dioxide and sodium chlorite pesticide-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of chlorine dioxide and sodium chlorite that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorine dioxide and sodium chlorite, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of chlorine dioxide and sodium chlorite, the Agency has determined that chlorine dioxide and sodium chlorite products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of chlorine dioxide and sodium chlorite. If all changes outlined in this document are incorporated into the product labels, then all current risks for chlorine dioxide and sodium chlorite will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for chlorine dioxide and sodium chlorite. During the public comment period on the risk assessments, which closed on June 26 ,2006, the Agency received comments from the registrants, Chlorine Dioxide Panel and other

interested parties. These comments in their entirety, as well as the risk assessments for chlorine dioxide, are available in the public docket (EPA-HQ-OPP-2006-0328) at http://www.regulations.gov/. The Agency's responses to these comments are incorporated into the risk assessment and revised chapters, which are also available in the public docket.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to sodium chlorite are within acceptable levels. In other words, EPA has concluded that the exemptions from tolerances for sodium chlorite meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to sodium chlorite from all possible sources.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with chlorine dioxide and sodium chlorite. The Agency has determined that, taking into consideration that a safety finding was made for sodium chlorate in the Inorganic Chlorates RED, the established tolerance exemptions for chlorine dioxide and sodium chlorite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of chlorine dioxide and sodium chlorite. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of chlorine dioxide and sodium chlorite. As discussed in Section III, the acute, and chronic dietary (food and drinking water) risks from chlorine dioxide and sodium chlorite are below the Agency's level of concern, provided that mitigation measures outlined in this document and the and the Inorganic Chlorates RED are adopted and labels are amended.

c. Determination of Safety to Infants and Children

EPA has determined that the tolerance exemptions for chlorine dioxide and sodium chlorite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of chlorine dioxide and sodium chlorite residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of chlorine dioxide/sodium chlorite, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA safety factor has been reduced to 1X for chlorine dioxide/sodium chlorite. The rational for the decisions are based on: (1) the existence of a complete developmental and reproductive toxicity database; (2) the endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide is protective of potentially susceptible populations including children and (3) the risk assessment does not underestimate the potential exposure for infants and children.

d. Endocrine Disruptor Effects

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of chlorine dioxide and sodium chlorite. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances

individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorine dioxide and sodium chlorite. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Reassessment Summary

Table 12 summarizes the reassessment of the chlorine dioxide tolerance exemptions for sodium chlorite.

In order to support the use of chlorine dioxide/sodium chlorite as a fruit and vegetable wash for Raw Agricultural Commodities that will not be processed, a petition to establish a tolerance exemption must be submitted.

a. Tolerances Currently Listed Under 40 CFR §180.940(b)(c) and Tolerance Reassessment

Table 12. Tolerance Information Listed Under 40 CFR 180.1070

Expression	Commodity	Current Tolerance	Tolerance Reassessment	Use
Sodium chlorite	*Brassica* (cole) leafy vegetables	Exempt	Exempt [1]	seed soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes
Sodium chlorite	Radishes	Exempt	Exempt [1]	seed soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes
Tolerance Exemption Expression	**CAS No.**	**40 CFR**	**Use Pattern**	**Limits**

Oxychloro species(including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	N/A	180.940 (b)[2](c)[3]	Food-contact surface sanitizing solution	When ready for use, the end-use concentration is not to exceed 200 ppm chlorine dioxide
Tolerance Exemption Expression	**CAS No.**	**40 CFR**	**Use Pattern**	**Limits**
Oxychloro species (predominately chlorite, chlorate and chlorine dioxide in an equilibrium mixture) generate either (i) by directly metering a concentrated chlorine dioxide solution prepared just prior to use, into potable water, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominately chlorite and chlorate) followed by dilution with potable water	N/A	180.940 (c)[3]	Food-contact surface sanitizing solution	When ready for use, the end-use concentration is not to exceed 200 ppm chlorine dioxide

1. Residues listed under 40 CFR §180.1070 are exempted from the requirement of a tolerance when used as a seed soak treatment in the growing of the raw agricultural commodities group listed
2. Under 40 CFR §180.940(b), chemical substances when use as ingredients in an antimicrobial pesticide formulation may be applied to dairy processing equipment, and food-processing equipment and utensils.
3. Under 40 CFR §180.940 (c), chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to food-processing equipment and utensils.

b. Codex/International Harmonization

There are no Codex maximum residue limits (MRLs) for sodium chlorite.

D. Regulatory Rationale

The Agency has determined that chlorine dioxide and sodium chlorite are eligible for reregistration provided that additional required data confirm this decision and that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of chlorine dioxide and sodium chlorite. Where labeling revisions are warranted, specific language is set forth in the Table 13 of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Acute Dietary (Food) Risk

No acute dietary endpoint was selected because effects attributable to a single dose were

not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

Chronic Dietary (Food) Risk

Although there is not a concern for chronic dietary risk estimates for all populations. Dietary exposure from food did have an impact of the aggregate assessment for children which is of concern (MOE = 44). The individual exposure received from the post-harvest application of sodium chlorite to fruits and vegetables is an extremely high-end estimate. This assessment was conducted with the most conservative assumptions and resulted in an estimate of 42% of the cPAD for children. For example, this assessment assumed that all fruits and vegetables in the U.S. had a chlorine dioxide solution applied and that these commodities were not washed, cooked or processed prior to consumption. Additionally, the Chlorine Dioxide Panel has agreed to limit the residual concentration of chlorine dioxide to 3 ppm for post-harvest application to fruits and vegetables that are not raw agricultural commodities. Therefore, fruits and vegetables treated with chlorine dioxide must be followed by blanching, cooking or canning. Although the Agency cannot quantify the reduction of chlorine dioxide dietary exposure at this time, it is believed that this measure would significantly reduce the percent of chlorine dioxide cPAD resulting from this use. No additional dietary risk mitigation measures are required to address exposure to chlorine dioxide and sodium chlorite residues in food. Further, these conservatisms and label changes also mitigate the aggregate risks to children so that they are no longer of concern.

b. Safe Drinking Water Act

When determining whether a pesticide tolerance is safe, EPA must consider the factors listed in section 408(d) of the FFDCA. One of these factors is the consideration of other non-occupational pesticidal exposures. For chlorine dioxide and sodium chlorite, exposures occur through drinking water from treatment plant disinfection. These exposures need to be considered when reassessing the tolerances associated with the registered uses of these pesticides.

Chlorine dioxide and sodium chlorite are used to disinfect water in treatment plants in order to meet the Safe Drinking Water Act's (SDWA) requirements to protect drinking water. In addition to the statute, 40 C.F.R. section 141.72 states, "A public water system that uses a surface water source and does not provide filtration treatment must provide the disinfection treatment . . . ." The required residual of the disinfectant chlorine dioxide is specified in 40 C.F.R. 141.74.

The SDWA was originally passed by Congress in 1974 to protect public health by regulating the nation's public drinking water supply. The law was amended in 1986 and 1996 and requires many actions to protect drinking water and its sources: rivers, lakes, reservoirs, springs, and ground water wells. (SDWA does not regulate water systems, which serve fewer than 25 individuals.) SDWA authorizes the EPA to set national health-based standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. EPA, states, and water systems then work together to make sure that these standards are met.

Drinking water that is not properly treated or disinfected, or which travels through an improperly maintained distribution system, may pose a health risk. SDWA applies to every public water system in the United States. The responsibility for making sure these public water systems provide safe drinking water is shared among EPA, states, tribes, water systems, and the public.

EPA sets national standards for drinking water based on sound science to protect against health risks, considering available technology and costs. These National Primary Drinking Water Regulations set enforceable maximum contaminant levels (MCL) for particular contaminants in drinking water or required ways to treat water to remove contaminants. Each standard also includes requirements for water systems to test for contaminants in the water to make sure standards are achieved. As listed in 40 CFR 141.53 EPA has set the MCL at 0.1 mg/L for sodium chlorite.

To ensure that drinking water is safe, SDWA sets up multiple barriers against pollution. One such barrier is treatment. Public water systems are responsible for ensuring that contaminants in tap water do not exceed the standards. Water systems treat the water, and must test their water frequently for specified contaminants and report the results to states. If a water system is not meeting these standards, it is the water supplier's responsibility to notify its customers.

EPA sets primary drinking water standards through a three-step process:

- First, EPA identifies contaminants that may adversely affect public health and occur in drinking water with a frequency and at levels that pose a threat to public health. EPA identifies these contaminants for further study, and determines contaminants to potentially regulate.
- Second, EPA determines a maximum contaminant level goal for contaminants it decides to regulate. This goal is the level of a contaminant in drinking water below which there is no known or expected risk to health. These goals allow for a margin of safety.
- Third, EPA specifies a maximum contaminant level, the maximum permissible level of a contaminant in drinking water which is delivered to any user of a public water system. These levels are enforceable standards, and are set as close to the goals as feasible. SDWA defines feasible as the level that may be achieved with the use of the best technology, treatment techniques, and other means which EPA finds (after examination for efficiency under field conditions) are available, taking cost into consideration. When it is not economically or technically feasible to set a maximum level, or when there is no reliable or economic method to detect contaminants in the water, EPA instead sets a required Treatment Technique which specifies a way to treat the water to remove contaminants.

EPA sets national standards for tap water which help ensure consistent quality in our nation's water supply. EPA prioritizes contaminants for potential regulation based on risk and how often they occur in water supplies. (To aid in this effort, certain water systems monitor for the

presence of contaminants for which no national standards currently exist and collect information on their occurrence). EPA sets a health goal based on risk (including risks to the most sensitive populations, e.g., infants, children, pregnant women, the elderly, and the immuno-compromised). EPA then sets a legal limit for the contaminant in drinking water or a required treatment technique. This limit or treatment technique is set to be as close to the health goal as feasible.

EPA also performs a cost-benefit analysis and obtains input from interested parties when setting standards.

EPA promulgated regulations to control microbial pathogens and disinfectants/disinfection byproducts in drinking water in a multi-stage process that dates back to a 1992-93 negotiated rulemaking, which was affirmed by Congress in the 1996 Amendments to the SDWA. The regulations address complex risk trade-offs between the two different types of contaminants and were promulgated with significant stakeholder input. (65 FR 83016)

Even though, the FFDCA standard in section 408 is a risk-based standard and the SDWA is a cost-benefit standard, the Agency believes we must consider the harm to human health broadly. In doing so, the EPA does not believe it to be prudent to cancel the drinking water disinfectant use of chlorine dioxide and sodium chlorite as that action could potentially result in harming the public at large. The Agency believes the mitigation measures required in this document for the food uses that require pesticide tolerances will reduce exposures from those uses such that the exposures will result in a minimal addition to the exposure that occurs from drinking water. The Agency is reasonably certain that this minimal addition does not cause harm to human health, and is therefore safe under section 408(b) of the FFDCA.

c. Drinking Water Risk Mitigation

Drinking water risks of concern were identified for infants. Drinking water exposure also played a role in the aggregate risks of concern for children.

The chlorite ion (ClO_2^-) is a major degradation product resulting from the reaction of chlorine dioxide with inorganic and organic constituents in the water. When free chlorine is used after the application of chlorine dioxide in the treatment process, chlorite is oxidized to chlorate. Chlorite oxidizes to chlorate over a period of time in water and soil. This conversion will continue over time as the water travels through the distribution system. Treatment of public water supplies is necessary to kill pathogens that may exist in the drinking water, such as cholera, typhoid, and dysentery. Outbreaks of these diseases decreased significantly when disinfection of the water systems was introduced in the early 1900s. While there are many important public functions of water treatment, the Agency is taking steps to limit the exposure of chlorite ion as a disinfection byproduct to the public. Approximately six percent of U.S. water treatment facilities use chlorine dioxide for water disinfection.

In addition, the Chlorine Dioxide Panel recently submitted a study that evaluated whether the components of the baby formula react with the chlorite in drinking water to form chloride, which is not of concern in drinking water because it is easily absorbed and metabolized by the

body. A preliminary review of the data suggests that the components of the baby formula, such as ascorbic acid, react with chlorite in the drinking water. Specifically, within five minutes of adding the formula to the water, approximately one third of the chlorite combines with the ingredients in the infant formula to form chloride.

The Agency is not currently able to quantify the reduction of exposure to chlorite that occurs due to binding of chlorite with ingredients present in the baby formula. However, based on its initial evaluation of the existing data, the Agency believes that for all infants the % cPAD will likely be close to the target of 100, and not of concern. The Agency will require additional data on the breakdown of chlorite in baby formula as confirmatory data.

As mentioned above, the aggregate risks to children 1-6 are mitigated by the consideration discussed concerning dietary exposures from food.

d. Residential Risk Mitigation

i. Residential Handler

Residential risks for handlers were calculated for short- and intermediate-term dermal and inhalation exposures. Risks of concern were identified for homeowners who place tablets in swimming pools/spas with their bare hands (MOE=46). This risk will be mitigated if the homeowner wears gloves while placing the tablet in the swimming pool/spa (MOE=500). Although the Agency does not normally require the use of personal protective equipment such as gloves, on pesticidal products that are used in and around the home, the use of gloves in this case is thought to be prudent since the Agency expects that, given the nature of pool products of this kind, residents are likely to wear gloves based on a perception of the danger of the chemicals along with the label warnings and precautions. This is not necessarily expected to be true of most other residential products where Personal Protective Equipment (PPE) would not be considered an effective mitigation measure nor should this be viewed as a precedent for requiring use of PPE for residential use products. All other exposure and risk estimates for residential handler scenarios are below the Agency's level of concern.

ii. Residential Post-Application

The Agency has conducted dermal, incidental oral and inhalation exposure assessments for residential post-application scenarios.

The residential use of chlorine dioxide/sodium chlorite continuous release deodorizers are of concern. To mitigate this risk, the following use sites for the continuous release deodorizer are ineligible for reregistration and must be deleted: shoes, closets, laundry hampers, bags, drawers, basements, boat cabins, trash bags, and additional deodorizing uses. The remaining use sites will be in an outdoor or commercial setting where people are not likely to have prolonged exposure, e.g., dumpsters. Therefore, the risks from this use pattern would be considered to be no longer of concern. The registrant has agreed to voluntarily cancel these use patterns.

Based on the risk assessment, a post-application inhalation concern was identified for adults and children exposed to carpets treated with chlorine dioxide/sodium chlorite. In order to mitigate this risk, the registrants must prohibit residential use; however, a commercial application to carpet will remain registered with a one hour Restricted Entry Interval (REI).

e. Aggregate Risk Mitigation

Intermediate- and Short-Term

The short- and intermediate- risks to infants are primarily driven by exposure to residues in drinking water. These exposures and risks are mitigated as described in the drinking water section above. The short- and intermediate- risks to children are largely driven by the dietary exposure through food. The characterization and mitigation described above for risks from exposure to residues in food address the aggregate risk as well. Based on these characterization and mitigation measures, the Agency believes that aggregate risks are not of concern.

Chronic

The chronic risks to infants are primarily driven by exposure to residues in drinking water. These exposures and risks are mitigated as described in the drinking water section above. The chronic risks to children are largely driven by the dietary exposure through food. The characterization and mitigation described above for risks from exposure to residues in food address the aggregate risk as well. Based on these characterization and mitigation measures, the Agency believes that aggregate risks are not of concern.

f. Occupational Risk Mitigation

i. Occupational Handler

Dermal Risks from Applications in Agricultural and Medical Premises

The Agency has conducted dermal and inhalation exposure assessments for handlers applying chlorine dioxide in an occupational setting. Based on this assessment, dermal risks of concern were identified for handlers applying chlorine dioxide: to hard surfaces using a low pressure hand wand (MOE=31); to hard surfaces using a mop (MOE=70); to animal transport vehicles/tractor trailer using a foam application (MOE=8 w/ gloves); and in food handling, commercial/institutional, and medical premises and equipment using a mop (MOE=66 for commercial and MOE=3 for medical).

These scenarios were evaluated using highly conservative assumptions including the use of a 100% dermal absorption factor that assumes that all chlorine dioxide/sodium chlorite that contacts the skin will be absorbed. Further, high-end application and use parameters were used to develop the risk estimates. Therefore, the Agency does not expect that actual exposures would be as high as those calculated in the risk assessment.

For these scenarios, the risks will be mitigated by requiring handlers to wear gloves during application. Although there is no data to assess most scenarios with handlers wearing gloves, the Agency is confident that this mitigation will protect occupational handlers. Therefore, these risks are not of concern to the Agency.

For the foam application, the Chlorine Dioxide Panel has submitted information indicating that the Agency has overestimated the risks associated with this use. Specifically, the information indicates that the number of vehicles treated in a day is eight, using two quarts of solution per vehicle. The Agency assessed an application rate of 4 to 6 gallons per minute and assumed that this product was applied for ten minutes per day. Subsequently, EPA determined that the assessed application rate was too high. Based on the revised application rate, the Agency does not have a concern with this risk, provided that gloves are worn during the treatment. Additional details can be found in "*Chlorine Dioxide Occupational and Residential Exposure Assessment*," dated August 2, 2006.

Dermal Risks from Swimming Pool Applications

Occupational risks for handlers were calculated for short- and intermediate-term dermal exposures. Risks of concern were identified for handlers who place tablets in public swimming pools with their bare hands (MOE=5). This risk will be mitigated if the handlers wear gloves while placing the tablet in the swimming pool (MOE=120), and no additional mitigation is required.

Inhalation Risks from Non-fogging Applications

There is the potential for the off-gassing of chlorine dioxide during some non-fogging occupational applications that are not totally enclosed (e.g., aqueous solution sprays, mopping, open pouring, etc). To address the potential for inhalation exposure, EPA has obtained worker air concentration measurements from OSHA for 7 industry Standard Industrial Classification (SIC) codes. The monitored air concentrations for workers are stored in OSHA's data base known as the Integrated Management Information System (IMIS). The inhalation endpoint selected by EPA for an 8-hour time-weighted average (TWA) is 0.003 ppm, just below OSHA's limit of detection of 0.004 ppm. Of the 33 TWA measurements available in IMIS, 21 of those measurements were below the limit of detection. In addition, of the 33 TWA measurements, only 3 were at or above the OSHA PEL of 0.1 ppm. At this point in time, monitoring to EPA's level of concern (i.e., 0.003 ppm) is not technically feasible. However, 64 percent of the samples indicate that the air concentrations of chlorine dioxide are near or below the level of concern. Therefore, for non fogging uses of chlorine dioxide such as open pouring of aqueous solutions or bystanders in pulp and paper mills no additional mitigation is deemed necessary at this time.

Inhalation Risks from Fogging Applications

Inhalation exposure to the release of chlorine dioxide gas during the mixing/loading/application of products producing chlorine dioxide may occur. There is a greater potential for chlorine dioxide gas formation from fogging then an aqueous-based application

such as mopping. The air concentration in a fogged area should be below the occupational RfC of 0.003 ppm before the room is entered by persons not wearing respiratory protection.

However, one scenario based on labeled application rates allows chlorine dioxide fogging and misting applications while workers are in the room if the level of chlorine dioxide does not exceed the TLV-TWA of 0.1 ppm. Based on this scenario, the occupational RfC of 0.003 ppm could be exceeded if handlers are present. Therefore, people must vacate the premises during fogging treatments and a one-hour restricted entry interval (REI) is required to address this risk.

2. Environmental Risk Management

Environmental risk for the once-through cooling tower use of chlorine dioxide/sodium chlorite has been assessed because it has the most potential for environmental exposure. The risk assessment was conducted using sodium chlorite endpoints because under environmental these conditions, chlorine dioxide converts mostly into chlorite ions.

Acute risk is anticipated for aquatic organisms from the use of chlorine dioxide/sodium chlorite in once-through cooling towers. At the highest doses on current labels (25 ppm), there is risk to freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates. To mitigate this risk, the maximum application rate for this use pattern must be reduced from 25 ppm to 5 ppm for intermittent applications.

Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described above is submitted, chronic risk to these organisms will be assessed. All other exposure and risk estimates are below the Agency's level of concern.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing chlorine dioxide and sodium chlorite. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Threatened and Endangered Species Considerations

a. The Endangered Species Program

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat.

To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The screening level model used in this assessment indicates that there may be acute risks to listed aquatic organisms from the once through cooling tower use of chlorine dioxide/sodium chlorite. Further, potential indirect effects on any species dependent upon a species that experiences effects from use of chlorine dioxide/sodium chlorite cannot be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Due to these circumstances, the Agency defers making a determination for the cooling tower use of chlorine dioxide and sodium chlorite until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the cooling tower of chlorine dioxide will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

Chlorine dioxide and sodium chlorite end use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing Chlorine dioxide and sodium chlorite specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) must be adopted.

V. What Registrants Need to Do

The Agency has determined that chlorine dioxide and sodium chlorite are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 13). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For chlorine dioxide and sodium chlorite technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and,

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive
Arlington, VA 22202

For end use products containing the active ingredient chlorine dioxide and sodium chlorite, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (PDCI response form and requirements status and registrant's response form); and,

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (CSF) (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 15 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and,

6. The product-specific data responding to the PDCI.

Please contact Emily Mitchell at (703) 308-8583 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PM-32)
Emily Mitchell
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PM-32)
Emily Mitchell
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of chlorine dioxide and sodium chlorite has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements. A generic data call-in will be issued at a later date. Several Ecological studies are being required to support the once-through cooling tower use of chlorine dioxide/sodium chlorite.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

Table 15. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Fish early life-stage testing-freshwater	850.1300	72-4
Invertebrate life-cycle testing - freshwater	850.1400	72-4b
Seedling emergence dose-response in rice	850.4225	123-1
Vegetative vigor dose-response in rice	850.4250	123-1
Aquatic vascular plant dose-response toxicity- *Lemna* sp.	850.4400	123-2
Acute algal dose-response toxicity - 4 species	850.5400	123-2
Indoor Inhalation Exposure and Applicator Exposure Monitoring Data Reporting	875.1400 and 875.1600	234 and 236
Indoor Dermal Exposure and Applicator Exposure Monitoring Data Reporting	875.1200 and 875.1600	233 and 236
Descriptions of Human Activity	875.2800	133-1
Carcinogenicity	870.4200	83-2
Fate of chlorite in baby formula	Special study	Special study
Use and Usage Information on the Percent of Fruits and Vegetables that are treated with Chlorine Dioxide		

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 16, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, will follow this RED at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above.

Specific language to incorporate these changes is specified in Table 16.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 16. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Product		
Supported Use Sites	"Only for formulation into antimicrobial products for use in: agricultural/farm premises, structures, buildings, and equipment; dairy farm milk handling facilities, equipment, storage rooms, houses, and sheds; food processing plants, food handling, food distribution equipment and premises; eating establishments premises and equipment; commercial, institutional, and industrial premises and equipment (floors, walls, storage areas); domestic dwellings, food handling areas, indoor premises; and medical institutional critical care and non-critical care premises, human water systems, swimming pools and industrial processes and water systems." For Formulation into antimicrobial products for use in: animal transport vehicles, carpets, fountains/water displays/decorative ponds/, once- through and recirculating industrial commercial cooling water systems, pulp/paper mill water systems, and swimming pools, mushroom facilities/premises and equipment, egg handling equipment and rooms, egg washing treatment, chick room, poultry houses chiller water/carcass spray, food processing plants/equipment, dairies/breweries and bottling plants/equipment, fruit and vegetable rinse/process water and tank lines, potable drinking water, water storage systems (aircrafts boats, RVs, off-shore oil rigs), water filtration systems, ventilation systems.	Directions for Use
PPE		Precautionary Statements

Description	Amended Labeling Language	Placement on Label
Ecological Effects Language Required by the RED and PR Notice 93-10 and 95-1	"This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Environmental Hazard Statements
End Use Products Intended for Occupational Use		
Application Restrictions-For Occupational Handler -Dermal (*Application to hard surfaces*)	"Handlers applying chlorine dioxide in an occupational setting must wear gloves." • low pressure hand wand (hard surfaces) • mop (hard surfaces) • foam application (animal transport vehicles/tractor trailer) • mop (food handling, commercial/institutional and medical premises/equipment)	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Handler -Dermal (*Tablets into public swimming pools*)	"Occupational handler must wear gloves while placing the tablet in the swimming pool"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Handler – Inhalation (*Fogging Use*)	"People must vacate the premises during fogging treatments; a one-hour restricted entry interval (REI) is required."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

Description	Amended Labeling Language	Placement on Label
Application Restrictions-For Occupational – Inhalation *(Carpet Treatment)*	"Not for residential use. For nonresidential use, a one-hour restricted entry interval is required."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Post-Application *(Once through use)*	"Reduce the application rate from 25 ppm to 5 ppm for intermittent applications."	
End Use Products Intended for Residential Use		
Application Restrictions-For Residential Handler -Dermal *(Tablets into pools/spas)*	"Residential handler (homeowner) must wear gloves while placing the tablet in the swimming pool/spa"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Residential Post-Application – Inhalation *(Continuous release deodorizers)*	"Restrict to outdoor use only. Do not use indoors (e.g., use in shoes, closets, laundry hampers, bags, drawers, basements, boat cabins, trash bags, and any additional deodorizing uses)"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

Description	Amended Labeling Language	Placement on Label
Application Restrictions-For Residential Post-Application – Inhalation *(Carpet Treatment)*	"Residential use is prohibited."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Dietary		
Fruit and vegetable wash	"Fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

VI. APPENDICES

Appendix A - Chlorine Dioxide, PC Code 020503

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Agricultural Storage Facilities (Containers, Trailers, Rail Cars, Vessels)	Soluble Concentrate 9150-11	Foaming Wand	One quart to system that delivers 4-6 gallons per minute of dilution water 10 minutes contact time	Preclean with water to remove debris and dirt.
Mushroom Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Picking Baskets	Soluble Concentrate 9150-2, 9150-3 9804-1, 58300-16, 58300-19	Flush equipment with sanitizing solution	Use-solution calls for 100-200 ppm total available chlorine dioxide	Clean equipment and surfaces thoroughly using a suitable detergent and rinse with water before sanitizing.
Mushroom Facilities (non-food contact): disinfect walls ceilings and floors	Soluble Concentrate 9150-2, 9150-3 9804-1, 58300-16, 58300-19	Spraying device	300-500 ppm total available chlorine dioxide 1,000 ppm for control of mold and slime on walls	Remove all gross filth from areas prior to disinfection. Never reuse activated solutions Avoid contact with food or food contact surfaces.
Potato Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Handling equipment	Soluble Concentrate 9804-1	Fill, flush, immerse or spray	Use-solution calls for 100 ppm total available chlorine dioxide	None stated
Potato Facilities: walls, ceilings floors, planting and harvesting equipment and truck beds	Soluble Concentrate 9804-1	Spray	10 minute contact time	Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Disinfection				
Potato Facilities: potato rinse tanks, flumes and lines	Soluble Concentrate 9804-1	Chemical Feed pump or injector system	5 ppm	After Treatment Potatoes must be rinsed with potable water.
Potato Storage: Potato rinse and humidification water	Soluble Concentrate 9804-5 9150-12	Spray, mist and fogger	200 to 400 ppm	No more than 20 gallons of product concentrate per month to humidification water per 500 tons of potatoes in storage. Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.
Disinfection of Animal Confinement Facilities (Poultry Houses, Swine Pens, Calf Barns and Kennels	Soluble Concentrate 9150-2, 9150-3 9804-1	Use Commercial Sprayer to saturate all surfaces	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Remove all animals and feed from premises. Remove all litter and manure from premises of facilities. Empty all troughs , racks and other feeding equipment/ watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water.
	Soluble Concentrate 9150-11	None Stated	1000 ppm	Remove all animals, bedding, litter, droppings and manure. Pre-clean
Animal Transport Vehicles	Soluble Concentrate 9150-11	Foaming Wand	One quart to system that delivers 4-6 gallons per minute of dilution water 10 minutes contact time	Preclean with water to remove debris and dirt.
Control for odor and Slime forming Bacteria in Animal Confinement Facilities	Soluble Concentrate 9150-2, 9150-3	Commercial sprayer to saturate all surfaces	1,000 ppm	Remove all litter and manure from premises and thoroughly clean all surfaces with soap or detergent and rinse with clean water

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Shoe Bath	Soluble Concentrate	Immersion	1 to 2 ounces per galloon of water	Change Shoe bath solution daily or when solution appears soiled.
Poultry House Disinfection: Poultry Chiller Water/ Carcass spray	Soluble concentrate 9150-2, 9150-3	Dip Carcass	0.5 to 3 ppm for Chiller Water 70 ppm for Carcass Spray	None stated
Poultry Drinking Water	Soluble concentrate 9150-2, 9150-3	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Egg Room/ Hatching Area Incubator Room Tray Washing Room and Loading Platform	Soluble Concentrate 9150-2, 9150-3	High pressure sprayer	20 ppm for pre wash w/ sprayer 390 ppm to preclean floors 1,000 ppm treatment w/ fogger	None Stated
	10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Chick Room, Chick Grading Box an Sexing room	Soluble concentrate 9150-2, 9150-3	Fogger, Mop	1,000 ppm w/ fogger 390 ppm to mop floors	None Stated
Hand Dip for Poultry Workers	Soluble concentrate 9150-2, 9150-3	Dip	50 ppm	None Stated
Horticulture uses Work Area and Benches	Ready to use Solution 9150-11	Cloth, mop, sponge or sprayer	9 fl oz per gallon/ 253 ppm	Do not Apply directly to Plant Material

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Horticulture uses Pots and Flats	Ready to use Solution 9150-11	Soak	18 fl oz per gallon/ 506 ppm	Remove all loose soil and plant residue prior to application
Horticulture uses Cutting Tools	Ready to use Solution 9150-11	Soak	9 fl oz per gallon/ 253 ppm	None Stated
Horticulture uses Bulbs	Ready to use Solution 9150-11	Soak	9 to 18 fl oz per gallon/ 253 ppm to 506 ppm	None Stated
Horticulture uses Greenhouse Glass, Walkways and under Bench Areas	Ready to use Solution 9150-11	Spray	4 to 9 fl oz per gallon/ 112 ppm to 253 ppm	None Stated
Evaporative Coolers	Ready to use Solution 9150-11	Add to water	4 to 9 fl. oz per gallon / 112 ppm to 253 ppm. Repeat as needed or every 14 days	None Stated
Rention Basins and Ponds	Ready to use Solution 9150-11	Add to Basin	4-9 fl oz. per 100 gallons/ 2 to 5 ppm	Do not use where fish are present
Decorative Pools, Fountains and Water Displays	Ready to use Solution 9150-11	Add to Pools	9-18 fl oz per 100 gallons/ 5 to 10 ppm	Do not use where fish are present.
Food handling/ storage establishments premises and equipment				
Food Processing Plants (Poultry, Meat, Fish) Food Contact Surface Sanitizer	Soluble Concentrate 9150-2, 9150-3 9804-9 9804-1	1 minute contact time	200ppm- 1,000 ppm total available chlorine Dioxide 50 ppm 100 ppm	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Food Processing Plants (Poultry, Meat, Fish) Non-Food contact disinfectant	Soluble Concentrate 9804-9 9804-1	Spray thoroughly wet for 10 minutes	500 ppm	Never reuse activated solutions
	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Dairies, Breweries and Bottling Plants Non-Food contact disinfectant	Soluble Concentrate, Ready to use Solution 9804-9 9804-1	Spray thoroughly wet for 10 minutes	500 ppm	Never reuse activated solutions
Dairies	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Dairies, Breweries and Bottling Plants Food Contact Surface Sanitizer	Soluble Concentrate, Ready to use Solution 9150-2, 9150-3 9804-9 9804-1	1 minute contact time	200ppm- 1,000 ppm total available chlorine Dioxide 50ppm 100ppm	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface
Ice Making Plants and Machinery	Soluble Concentrate, Ready to use Solution 9804-9	Chemical Feed Pump or Injector System	20 ppm	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	9804-1 9804-5			
Lube Additive for Moving Conveyors and Chains	Soluble Concentrate, Ready to use Solution 9804-9 9804-1	Inject into distribution system	10- 20 ppm	Preclean and sanitize all conveyor surfaces and associated structures
Canning Retort and Pasteurizer Cooling Water	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9	Controlled Chemical Feed Pump	5ppm	
Stainless Steel Transfer Lines, Hydrocoolers and Pasteurizers	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9 9804-1	Mix and fill lines and Equipment overnight	20 ppm	Preclean equipment or line thoroughly
Process Water for Vegetable Rinses, Tanks Lines	Soluble Concentrate 9150-2, 9150-3 9804-1	Chemical Feed Pump or injector system	5 ppm	Preclean all tanks, flumes and lines with suitable detergent.
Fruit and Vegetable Rinse	Soluble concentrate 9150-2, 9150-3 9804-1	Immersion	1/3 fl. to 1 gallon of water per 25 gallons of water 5 ppm	Prewash whole fruits and vegetables with clean potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Human Water Systems				
Potable Drinking Water	Ready to Use solution 59055-1	Metering Pump 1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	None Stated
	9150-2, 9150-3 9804-1 9804-5, 9150-9	None stated	5 ppm	None stated
Water Storage systems aboard Aircraft Boats, RV's Off-shore Oil Rigs	Soluble concentrate 9150-2, 9150-3 9804-1	Add to tank and lines	50 to 500 ppm available chlorine dioxide	None stated
Municipal Well Waters	9150-2, 9150-3	None stated	1 ppm	None stated
Commercial water filtration systems	9804-1	Add to system	300 ppm	None Stated
Commercial, institutional and industrial premises and equipment				
Dental Offices Dental Pumice Disinfectant	Soluble Concentrate 9150-3 9804-1	Apply to Dry Pumice	500 ppm	Discard 5 days after preparation
Hospitals and Nursing Homes Institutions and Public Places	Soluble Concentrate 10589-3,	Spray	1000 ppm to 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
General disinfectant	9150-11 9804-1			
Hospitals, Laboratories and Institutions Hard Non Porous surfaces (Tile Floors, Walls and Ceilings and Stainless Steel Cold Rooms)	Soluble Concentrate 9150-2, 9150-3 9804-1	Spray, Mop or sponge	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.
Disinfection of Bench Tops, Biological Hoods, Incubators, Stainless Steel Equipment and Instruments	Soluble Concentrate 9150-2, 9150-3 9804-1	Squirt onto surfaces with squeeze bottle	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.
Water Bath Incubator	Soluble Concentrate 9150-2, 9150-3 9804-1	Pour solution into waterbath reservoir	Working Solution containing 300 ppm available Chlorine Dioxide to disinfect 50 ppm for order and slime control	Clean reservoir with a suitable detergent and rinse with water prior to disinfection
Sterilzation of Spent Biologicals in Steam Autoclaves	Soluble Concentrate 9150-2, 9150-3	Spray or pour directly into autoclave buckets	Working Solution containing 1,000 ppm available Chlorine Dioxide	None Stated
To Deodorize Animal Holding Rooms, Sick Rooms, Morgues and	Soluble Concentrate	Spray solution on to walls ceilings and	Working Solution containing 1,000 ppm available Chlorine	Rooms to deodorize should be ina clean condition prior to autoclaving.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Work rooms	9150-2, 9150-3 9804-1	floors	Dioxide	
Industrial Processing Plants	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm	Remove gross filth and heavy soil prior to application of the disinfecting solution
Deodorizer- Hospitals, Restaurants, Hotel & Motel Rooms	Ready-to Use 9804-3	Spray	Spray area until covered with mist and let stand for 10 minutes	None stated
Swimming Pools				
Swimming Pools	Ready to use solution 59055-1	Meetering Pump	1 to 5ppm at a pH range from 7.2-7.6	None Stated
Residential and Public Access				
Odors on Pets, Litter Boxes, Carpets and Concrete Floors	Soluble concentrate 9150-2, 9150-3 9804-1	Soak, Mop or rinse	For litter boxes: 625 – 650ppm For carpets: 500 ppm Concrete floors: 1250 ppm Animal Baths: 80-100 ppm	Avoid direct contact with animal's eyes, nose and ears
Ice Fishing in the Round Treatment	Soluble Concentrate 9150-2, 9150-3 9804-1	None stated	20 ppm	None stated
Deodorizer- Restrooms/Bathrooms,	Ready-to Use	Spray	Spray area until covered with mist and let stand	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Refuse Containers, diaper Pails, Storage Lockers	9804-3		for 10 minutes	
Industrial Processes and Water Systems				
Water Cooling systems	Ready to Use, Soluble concentrate 59055-1 9804-9 9804-1	Batch load or meter	100 ppm 5.0 ppm	None Stated
Recirculating Cooling Water systems	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9	None stated	5-20 ppm	None stated
Water Based Cutting Oils	Soluble Concentrate 9150-2, 9150-3	Slug does system	32 oz to 10 gallons per million gallons of cutting oil	None stated
Paper Mills	Soluble Concentrate, Ready to use Solution 9150-2, 9150-3 9804-9, 9804-1	None stated	4.5 gallons product per 100 tons of paper 1.25 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated
Oil Wells : Secondary	Soluble	None Stated	5,000 ppm available	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Recovery Operations	Concentrate 9150-2, 9150-3		chlorine dioxide	
Once Through Water Cooling Systems	Soluble Concentrate 9150-2, 9150-3	Slug and Continuous	Slug Dose: 5-25 ppm Continuous Dose: 0.25 to 2.0 ppm	None Stated
Ventilation systems	Soluble concentrate 9804-1	Spray or fog	500 ppm. 10 minute contact time	NIOSH/MSHA approved respirator required

Appendix A - Sodium Chlorite 020502

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Mushroom Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Picking Baskets	Soluble Concentrate/ Ready to Use Solution 5382-46 58300-17 74602-2	Flush equipment with sanitizing solution	Use-solution calls for 100 ppm total available chlorine dioxide	Clean equipment and surfaces thoroughly using a suitable detergent and rinse with water before sanitizing.
Mushroom Facilities (non-food contact): disinfect walls ceilings and floors	Soluble Concentrate/ Ready to use Solution 5382-46 58300-17 69151-5 74602-2	Spraying device	500 ppm total available chlorine dioxide 1,000 ppm for control of mold and slime on walls	Remove all gross filth from areas prior to disinfection. Never reuse activated solutions Avoid contact with food or food contact surfaces.
Potato Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Handling equipment	Soluble concentrate: 53345-20, 56485-4	Fill, flush, immerse or spray	Use-solution calls for 100 ppm total available chlorine dioxide	None stated
Potato Facilities: potato rinse tanks, flumes and lines	Soluble concentrate: 53345-20, 56485-4, 9150-7	Chemical Feed pump or injector system	5 ppm	After Treatment Potatoes must be rinsed with potable water.
Potato Storage: Potato rinse and humidification water	Soluble concentrate: 53345-20, 56485-4,	Spray, mist and fogger	200 to 400 ppm	No more than 20 gallons of product concentrate per month to humidification water per 500 tons of potatoes in storage.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	21164-21			Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.
Disinfection of Animal Confinement Facilities (Poultry Houses, Swine farrowing pens, Calf Barns and Kennels	Soluble Concentrate 70060-18, 45631-23, 74602-2, 70060-6, 74602-3, 70060-19, 69151-5, 8714-8	Mop, sponge or Use Commercial Sprayer to saturate all surfaces	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Remove all animals and feed from premises. Remove all litter and manure from premises of facilities. Empty all troughs , racks and other feeding equipment/ watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water.
Agricultural premises and equipment				
Poultry House Disinfection: Poultry Chiller Water/ Carcass spray	Soluble Concentrate 74602-2 9150-7 9150-8 74602-3	Dip Carcass	0.11 to 0.33 ounces per gallon for Chiller Water or 50 to 150 ppm 500 to 1200 ppm for Carcass Spray	None stated
Poultry Processing Water	Soluble Concentrate, Ready to use Solution 21164-6 21164-8 21164-9 53345-19 53345-20 56485-4 74517-2 53345-21	None stated	3 ppm max	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	74517-1 74119-1			
Poultry Drinking Water	Soluble Concentrate 74602-2	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Poultry, swine, cattle and other livestock Drinking Water	Soluble Concentrate 64449-1	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Egg Room/ Hatching Area Incubator Room Tray Washing Room and Loading Platform	Soluble Concentrate 74602-2	High pressure sprayer	20 ppm for pre wash w/ sprayer 390 ppm to preclean floors 1,000 ppm treatment w/ fogger	None Stated
Egg Shells (Food Grade)	Soluble Concentrate 74602-2	Wet Thoroughly	5.0 ppm	Do not reuse solution
Chick Room, Chick Grading Box an Sexing room	Soluble Concentrate 74602-2	Fogger, Mop	1,000 ppm w/ fogger 390 ppm to mop floors	None Stated
Agricultural premises and equipment				
Horticulture uses Work Area and Benches	Soluble Concentrate 70060-6	Cloth, mop, sponge or sprayer	100 ppm	Do not Apply directly to Plant Material
Horticulture uses Pots and Flats	Soluble Concentrate	Soak	100 ppm	Remove all loose soil and plant residue prior to application

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	70060-6			
Horticulture uses Cutting Tools	Soluble Concentrate 70060-6	Soak	100 ppm	None Stated
Horticulture uses Bulbs		Soak	9 to 18 fl oz per gallon/ 253 ppm to 506 ppm	None Stated
Horticulture uses Greenhouse Glass, Walkways and under Bench Areas	Soluble Concentrate 70060-6	Spray	33 to 100 ppm	None Stated
Evaporative Coolers	Soluble Concentrate 70060-6	Add to water	100 ppm	None Stated
Food handling/ Storage establishments premises and equipment				
Non-Porous, Food Contact, hard surface sanitizer	Soluble concentrate: 74986-1, 70060-19, 21164-3, 21164-8, 21164-9, 5382-46	Foamer, Dilution device or spray	5ppm of activated available chlorine dioxide	None stated
Food Processing Plants (Poultry, Meat, Fish)	Soluble Concentrate 74602-2, 21164-3	fogger	0.5 ppm	Ventilate for 15 minutes prior to reentry
Food Processing Plants (Poultry, Meat, Fish) Food Contact Surface Sanitizer	Soluble concentrate: Reg:53345-14 53345-19 53345-20	1 minute contact time	50ppm- 1,000 ppm total available chlorine Dioxide	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	69151-3 70060-6 9150-7			
Food handling/ Storage establishments premises and equipment				
Fruit and Vegetables	Soluble Concentrate 9150-8	Spray or dip	500 to 1200 ppm	Rinse with potable water after treatment.
Dairies, Breweries and Bottling Plants	Soluble Concentrate 74602-2 74602-1	Fogger	0.5 ppm	Ventilate for 15 minutes prior to reentry
Dairies, Breweries and Bottling Plants Food Contact Surface Sanitizer	Soluble concentrate: 53345-14 53345-19 53345-20 9150-7 9150-8 21164-6 21164-8 21164-9 74602-2 5382-46 74517-1 53345-21 73139-1	1 minute contact time	50ppm- 1,000 ppm total available chlorine Dioxide	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Lube Additive for Moving Conveyors and Chains	Soluble concentrate: 74602-3, 21164-3	Inject into distribution system	10- 20 ppm	Preclean and sanitize all conveyor surfaces and associated structures
Canning Retort and Pasteurizer Cooling Water	Soluble concentrate: 70060-6, 74602-2, 70060-16, 53345-14, 9150-7, 9150-8, 46207-5, 5382-46	Controlled Chemical Feed Pump	0.1-5ppm	None stated
Food handling/ Storage establishments premises and equipment				
Stainless Steel Transfer Lines, Hydrocoolers and Pasteurizers	Soluble concentrate: 70060-6, 74602-2, 5382-46	Mix and fill lines and Equipment overnight	20 ppm	Preclean equipment or line thoroughly
Process Water for Vegetable Rinses, Tanks Lines	70060-6, 5382-46	Chemical Feed Pump or injector system	5 ppm	Preclean all tanks, flumes and lines with suitable detergent.
Fruit and Vegetable Rinse	Soluble concentrate: 45631-22, 45631-20, 74602-2, 45631-19, 53345-	Immersion, spray	1/3 fl. to 1 gallon of water per 25 gallons of water 3-5 ppm	Prewash whole fruits and vegetables with clean potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	20, 56485-4, 45631-22, 69151-5, 9150-7, 9150-8, 21164-21, 45631-19, 5382-46 79814-3			
Ice Making Plants and Machinery	Ready to use: 70060-13	Hang or place the sachet in the ice chamber out of direct contact with water or ice	50 to 200 g sachet per 100 to 400 lbs per day	None stated
	Soluble concentrate: 5382-46	Chemical Feed Pump or Injector System	20 ppm	None stated
Human Water Systems				

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Potable Drinking Water	Soluble concentrate: 53345-14 53345-19 53345-20 53345-22 69151-5 69151-3 70060-6 9150-7 9150-8 21164-6 21164-8 21164-9 21164-21 74602-2 5382-41 5382-42 5382-45 5382-46 74517-2 74517-1 53345-21 74602-1 79814-3	Metering Pump 1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	None Stated
		None stated	5 ppm	None stated
	Ready to use: 70060-22	Tablet	1 tablet per liter of water. Four hour treatment time.	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Water Storage systems aboard Aircraft Boats, RV's Off-shore Oil Rigs	Soluble concentrate: 74602-2 5382-46	Add to tank and lines	50 to 500 ppm available chlorine dioxide	None stated
Human Water Systems				
Municipal Well Waters	Soluble concentrate: 53345-23 55050-1 55050-2 70060-6 46207-5 74602-2 5382-46	None stated	1 ppm	None stated
Commercial, institutional and industrial premises and equipment				
Non-Porous, Non-food Contact, hard surface sanitizer	Soluble concentrate: 74986-1, 53345-13, 70060-19, 45631-15,	Dilution device or sprayer	100 ppm-200 ppm	
Odors on Pets, Litter Boxes, Carpets and Concrete Floors	Soluble concentrate: 70060-6, 70060-4	Soak, Mop or rinse	For litter boxes: 625 – 650ppm For carpets: 500 ppm	Avoid direct contact with animal's eyes, nose and ears

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
			Concrete floors: 1250 ppm Animal Baths: 80-100 ppm	
Residential				
Bathroom surfaces, shower stalls, curtains, laundry rooms, hampers and other non specified surfaces for mold and mildew control.	Soluble concentrate 74602-2	Spray, fog, pour, wipe	Dilute 13 fl. oz. solution as needed 5 minutes surface contact	After 30 minutes rinse with water
De-oderizer pouches for Refrigerators, Shoes, Gym Basements, Lockers, Laundry Hampers, Automobiles, Boat Cabins, athletic bags, trash cans pet areas, etc.	Ready to use Solution , Impregnated Materials 9804-10 70060-12	Hang or place sachet (deodorizing pouch)	5 to 200 grams sachet for use from 1 week to 2 months	None Stated.
Carpets	Ready to Use Powder 4822-512	Sprinkle on Carpet	2.5 oz per square yard.	Keep Children and pets off treated areas during application and until area is vacuumed.
Medical premises and equipment				
Hospitals, Laboratories and Institutions Hard Non Porous surfaces (Tile floors, Walls and Ceilings and Stainless	Soluble concentrate: 74602-2, 69151-1, 69151-5	Spray, Mop or sponge	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Steel Cold Rooms)				
Treatment of infectious medial waste (prior to disposal in a in a conventional solid waste landfill)	Soluble concentrate: 69972-1	Approved application system	None listed on label	None stated
Water Bath Incubator	Soluble concentrate: 74602-2, 70060-6	Pour solution into waterbath reservoir	Working Solution containing 300 ppm available Chlorine Dioxide to disinfect 50 ppm for odor and slime control	Clean reservoir with a suitable detergent and rinse with water prior to disinfection
Sterilization of Spent Biologicals in Steam Autoclaves	Soluble concentrate: 70060-6	Spray or pour directly into autoclave buckets	Working Solution containing 1,000 ppm available Chlorine Dioxide	None Stated
To Deodorize Animal Holding Rooms, Sick Rooms, Morgues and Work rooms	Soluble concentrate: 70060-6	Spray solution on to walls ceilings and floors	Working Solution containing 1,000 ppm available Chlorine Dioxide	Rooms to deodorize should be in a clean condition prior to autoclaving.
Swimming Pools				

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Swimming Pools	Tablet form, Ready to Use solution 70060-20	Tablet insert in hair and lint basket	1 tablet for under 10,000 gallons 2 tablets for over 10,000 gallons Apply every 3-4 weeks	Do not add this product through any automatic dispensing device. Apply product when no persons are in the pool.
Industrial Processes and water systems				
Waste water	Soluble concentrate: 53345-20, 55050-1 55050-2 56485-4 69151-4 69151-3 9150-7 10707-32 21164-6 21164-8 21164-9 21164-21 46207-5 5382-41 5382-43 5382-45 74119-1 74517-3 74517-2 53345-10	Batch load or meter	5.0 ppm to 100 ppm	None Stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	79814-3 53345-12 5382-42 74602-1			
Industrial Processes and water systems				
Water Cooling systems	Soluble concentrate: 53345-14 53345-19 53345-22 56485-4 69151-4 10707-32 46207-5 5382-46	Batch load or meter	5.0 ppm to 100 ppm	None stated
Industrial process water	Soluble concentrate: 53345-20 9150-7 21164-8 53345-21 74602-1	Batch load or meter	5.0 ppm to 100 ppm	NIOSH/MSHA approved respirator required
Water Based Cutting Oils	Soluble concentrate: 70060-6	Slug does system	32 oz to 10 gallons per million gallons of cutting oil	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Oil Wells : Secondary Recovery Operations	Soluble concentrate: 69151-3 68329-18 70060-6 10707-32 21164-3 5382-41 74602-3	None Stated	5,000 ppm available chlorine dioxide	None stated
Oilfield Injection	Soluble concentrate: 74602-1 79814-3	Shock dosage	200-3000ppm	None stated
Industrial Processes and water systems				
Recirculating Cooling Towers	Soluble concentrate: 74062-1 79814-3	Cooling tower drip pan	0.1 to 5.0 ppm 55.3 fl. oz per 1000 gallons of water for initial dosage 2.6 fl. oz per 100 gallons of water for subsequent dosage	None Stated
Once Through Water Cooling Systems	Soluble concentrate:	Slug and Continuous	Slug Dose: 5-25 ppm Continuous Dose: 0.25 to 2.0 ppm	None Stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	53345-14 53345-19 53345-20 69151-3 70060-6 9150-7 9150-8 1757-96 5382-41 5382-43 5382-45 74119-1 74517-2 53345-21 74602-1 79814-3			
Paper Mills	Soluble concentrate: 53345-22 56485-4 69151-4 69151-3 70060-6	None stated	4.5 gallons product per 100 tons of paper .01 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	74602-1 9150-7 9150-8 10707-32 21164-6 21164-8 21164-9 21164-21			
Industrial Processes and water systems				
Paper Mills	Soluble concentrate: 46207-5 5382-41 5382-42 5382-43 5382-45 74119-1 74517-2 53345-21 74655-2	None stated	4.5 gallons product per 100 tons of paper 1.25 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated

APPENDIX B: Chlorine dioxide and Sodium Chlorite* (Case 4023)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Chlorine Dioxide and Sodium Chlorite. These requirements apply to Chlorine Dioxide and Sodium Chlorite in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

(1) Agricultural premises and equipment
(2) Food handling/ storage establishments' premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming pools
Aquatic areas

3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column **(12)** will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	1-4, 5, 8, 11	41467601, 41467602
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	1-4, 5, 8, 11	41467601, 41467602
830.1670	61-2b	Formation of Impurities	1-4, 5, 8, 11	41467601, 41467602
830.1700	62-1	Preliminary Analysis	1-4,, 5, 8, 11	41467601, 41467602
830.1750	62-2	Certification of Limits	1-4, 5, 8, 11	41467601, 41467602
830.1800	62-3	Analytical Method	1-4, 5, 8, 11	41467601, 41467602
830.6302	63-2	Color	1-4, 5, 8, 11	41467601, 41467602
830.6303	63-3	Physical State	1-4, 5, 8, 11	41467601, 41467602
830.6304	63-4	Odor	1-4, 5, 8, 11	41467601, 41467602
830.7200	63-5	Melting Point	1-4, 5, 8, 11	41467601, 41467602
830.7220	63-6	Boiling Point	1-4, 5, 8, 11	41467601, 41467602
830.7300	63-7	Density	1-4, 5, 8, 11	41467601, 41467602
830.7840 830.7860	63-8	Solubility	1-4, 5, 8, 11	41467601, 41467602
830.7950	63-9	Vapor Pressure	1-4, 5, 8, 11	41467601, 41467602
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	1,4, 5, 8, 11	41467601, 41467602
830.7000	63-12	pH	1-4, 5, 8, 11	41467601, 41467602

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.6313	63-13	Stability	1-4, 5, 8, 11	41467601, 41467602
830.6314	63-14	Oxidizing/Reducing Action	1-4, 5, 8, 11	41467601, 41467602
830.6315	63-15	Flammability	1-4, 5, 8, 11	41467601, 41467602
830.6316	63-16	Explodability	1-4, 5, 8, 11	41467601, 41467602
830.6317	63-17	Storage Stability	1-4, 5, 8, 11	41467601, 41467602
830.6319	63-19	Miscibility	1-4, 5, 8, 11	41467601, 41467602
ECOLOGICAL EFFECTS				
850.1300	72-4	Fish early life-stage testing-freshwater		Data gap
850.1400	72-4b	Invertebrate life-cycle testing - freshwater		Data gap
850.4225	123-1	Seedling emergence dose-response in rice		Data gap
850.4250	123-1	Vegetative vigor dose-response in rice		Data gap
850.4400	123-2	Aquatic vascular plant dose-response toxicity- *Lemna* sp.		Data gap
850.5400	123-2	Acute algal dose-response toxicity - 4 species		Data gap (only one species tested-MRID 41880403)
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		ACC259373,ACC257341, ACC253378, MRID 31610, ACC254177, ACC252854
850.1075	72-1	Fish Acute Toxicity – Freshwater (Rainbow Trout)		MRID94068007, ACC254181, ACC254180, ACC252854, ACC245697, ACC69810, ACC253379, MRID94068006
850.1010	72-2	Acute Aquatic Invertebrate Toxicity		MRID146162, MRID141149, MRID131350, ACC254182, MRID94068009

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TOXICOLOGY*				
870.1100	81-1	Acute Oral - Rat		MRID 43558601
870.1200	81-2	Acute Dermal - Rabbit		MRID 40168704
870.1300	81-3	Acute Inhalation - Rat		MRID 42484101
870.2400	81-4	Primary Eye Irritation - Rabbit		MRID 43441903
870.2500	81-5	Primary Dermal Irritation - Rabbit		MRID40168704
870.2600	81-6	Dermal Sensitization		Data gap
870.3100	82-1a	90-Day Oral (gavage) -Rat		MRID 42301601
870.3465	82-4	28/90-Day Inhalation - Rat		Open literature
870.3700	83-3	Developmental Toxicity -Rat		Open literature
870.3700	83-3	Developmental Toxicity - Rabbit		MRID 41715701
870.3800	83-4	Two-generation Reproduction - Rat		MRID 45358901
870.5265	84-2	Bacterial Reverse Mutation Assay		Open literature
870.5300	84-2	Detection of gene mutations in somatic cells		ACC265867
870.5385	84-2	Micronucleus Assay		Open literature
870.4200	83-2	Carcinogenicity		Data gap

**** Databases for chlorine dioxide and sodium chlorite were used interchangeably.***

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket located in Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the draft risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered all comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov, docket ID # **EPA-HQ-OPP-2006-0328.**

These documents include:

1. Chlorine Dioxide Draft Risk Assessment, 4/6/2006.
2. Chlorine Dioxide Toxicology Disciplinary Chapter, 4/5/2006.
3. Chlorine Dioxide Occupational and Residential Exposure Assessment, 4/5/2006.
4. Chlorine Dioxide Environmental Fate and Transport Assessment, 4/5/2006.
5. Chlorine Dioxide Product Chemistry Chapter, 4/5/2006.
6. Chlorine Dioxide Dietary Exposure Assessment, 4/6/2006.
7. Chlorine Dioxide Environmental Hazard and Risk Assessment, 4/6/2006.
8. Chlorine Dioxide Incident Reports, 2/23/2006.
9. Chlorine Dioxide Environmental Modeling Chapter, 6/28/2005.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Chlorine Dioxide Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

1. MRID Studies

MRID #	Citation
31610	Fletcher, D. 1973. Acute Oral Toxicity Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Industrial BIO-TEST Laboratories, Inc. for Olin Corporation.
69809	1978. Acute Toxicity of Sodium Chlorite to Bluegill (*Lepomis macrochirus*). Unpublished Data. Conducted by EG&G, Bionomics, Aquatic Toxicology Laboratory for Olin Chemicals.
69810	1979. Acute Toxicity of Sodium Chlorite to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by EG&G, Bionomics, Aquatic Toxicology Laboratory for Olin Chemicals.
80194	Sousa, J.V. 1981. Acute Toxicity of Sodium Chlorite to Bluegill(*Lepomis macrochirus*). Unpublished Data. Conducted by EG&G, Bionomics for Olin Chemicals.
118007	Sousa, J.V. and D.C. Surprenant. 1984. Acute Toxicity of AC-66 to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Springborn Bionomics, Inc. for Calgon Corporation.
130649	Fink, R. 1977. Eight-day Dietary LC50 - Bobwhite Quail – Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for Olin Corporation.
130650	Fink, R. 1977. Eight-day Dietary LC50 – Mallard Duck – Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for Olin Corporation.
131350	Vilkas, A.G. 1976. Acute Toxicity of Textone to the Water Flea *Daphnia magna* Strauss. Unpublished Data. Conducted by Aquatic Environmental Sciences for Olin Corporation.
131351	Sleight III, B.H. 1971. Acute Toxicity of Sodium Chlorite to Bluegill (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Bionomics, Inc.
141149	Hoberg, J.R. and D.C. Surprenant. 1984. Acute Toxicity of AC-66 to Daphnids (*Daphnia magna*). Unpublished Data. Conducted by Springborn Bionomics, Inc. for Calgon Corporation.

141151 Fletcher, D. 1984. 8-Day Dietary LC50 Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

141152 Fletcher, D. 1984. Acute Oral Toxicity Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

142327 McMillen, C. 1984. Static Bioassay on Sodium Chlorite to Rainbow Trout and Bluegill Sunfish. Unpublished Data. Conducted by Environmental Research Group, Inc. for Rio Linda Chemical Company, Inc.

143970 Fletcher, D. 1984. 8-Day Dietary LC50 Study with Sodium Chlorite in Mallard Ducklings. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

144730 Robaidek and Johnson, 1985. Avian Single-dose Oral LD50: Bob White Quail (*Colinus virginianus*). Unpublished Data. Conducted by Hazleton Laboratories America, Inc. for Rio Linda Chemical Company.

145405 Beavers, 1984. An Acute Oral Toxicity Study in the Mallard with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145406 Beavers, 1984. An Acute Oral Toxicity Study in the Bobwhite with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145407 Beavers, 1984. A Dietary LC50 Study in the Mallard Duck with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145408 Beavers, 1984. A Dietary LC50 Study in the Bobwhite with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145409 Larkin, J. 1984. The Acute Toxicity of Sodium Chlorite to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

145510 Larkin, J. 1984. The Acute Toxicity of Sodium Chlorite to Bluegill Sunfish (*Lepomis macrochirus*). Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

145411 Larkin, J. 1984. Acute Toxicity of Sodium Chlorite to *Daphnia magna* Strauss. Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

146162 Barrows, 1984. The Acute Toxicity of Sodium Chlorite Technical to the Water Flea, *Daphnia magna* in a Static Test System. Unpublished Data. Conducted by Biospherics Incorporated for Degussa Corporation.

148727 Robaidek, E. 1985. Avian Single-Dose Oral LD_{50} Bobwhite Quail. Unpublished Data. Conducted by Hazleton Laboratories America, Inc. for Degussa Corporation.

161875 1984. 96-Hour LC50 in Juvenile Rainbow Trout. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

161876 1984. 48-Hour LC50 in *Daphnia magna*. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

161877 1984. Avian Dietary LC50 in Bob White Quail. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Chlorine Dioxide RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Chlorine Dioxide and Sodium Chlorite Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency intends to complete batching at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/ .

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

   c. EPA Form No. 8570-27, Formulator's Exemption Statement

   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: http://npic.orst.edu .

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.